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Reliability and Validity of Health-Related Quality of Life Instruments for Breast Cancer Patients in Asia: A Systematic Review and Meta-Analysis

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KEYWORDS

HRQoL, breast cancer, reliability, validity, EORTC QLQ-C30, QLQ-BR23, FACIT-Sp12, meta-analysis, Asia.

ABSTRACT

Health-related quality of life (HRQoL) instruments are crucial for assessing breast cancer patients' well-being. This research reviewed and meta-analyzed the reliability and validity of widely used HRQoL instruments, including EORTC QLQ-C30, QLQ-BR23, and FACIT-Sp12, in Asian breast cancer populations. Searches in PubMed, Embase, and Web of Science up to November 2024 identified five studies with 818 patients. Reliability was assessed using Cronbach's alpha, with pooled values calculated via a random-effects model. EORTC QLQ-C30 and QLQ-BR23 showed strong reliability, with pooled Cronbach's alpha values of 0.881 (I^2 = 93%) and 0.860 (I^2 = 90%), respectively, while FACIT-Sp12 demonstrated excellent reliability (α = 0.87). High heterogeneity in EORTC QLQ-C30 and QLQ-BR23 results likely stemmed from population and research design variations. Validity data were inconsistently reported but highlighted QLQ-BR23's superior item discriminant validity and QLQ-C30's strong construct validity (CVI = 0.98). These instruments are reliable tools for HRQoL assessment in Asian breast cancer populations. However, variability in validity reporting and significant heterogeneity limit their universal applicability. To enhance their use in Asia, future studies should standardize validity methodologies, address heterogeneity sources, and consider cultural diversity. Additionally, digital adaptations and resource-sensitive approaches are needed to make these tools more accessible in diverse and resource-limited settings. This will ensure more accurate and equitable assessments of HRQoL across Asia.

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INTRODUCTION

Breast cancer remains the most common cancer among women worldwide, with a substantial burden observed in Asia due to its diverse populations, healthcare systems, and cultural contexts (Yap et al., 2019). Evaluating health-related quality of life (HRQoL) in breast cancer patients is essential for understanding their overall well-being during and after treatment. Reliable and valid HRQoL assessment tools are critical, especially as the HRQoL of breast cancer patients in Asia is often reported to be lower than that of the general population (Salas et al., 2022).

In Asia, the region's cultural and linguistic diversity underscores the need for HRQoL questionnaires that are not only reliable and valid but also appropriately adapted to its unique sociocultural contexts (Zaki et al., 2025). Widely used tools, such as the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), Functional Assessment of Cancer Therapy-Breast (FACT-B), and Breast Cancer-Specific Quality of Life Questionnaire (QLQ-BR23), exhibit variability in their psychometric properties and applicability across different settings. Despite the availability of these tools, the lack of standardized validation methodologies tailored for Asia has resulted in inconsistent adaptation and use, further complicating

cross-research comparisons and hindering the development of region-specific clinical and research practices (Jerbi, 2025).

This systematic review and meta-analysis aimed to evaluate the reliability and validity of HRQoL questionnaires used for breast cancer patients in Asia (Sun et al., 2023). By comparing the psychometric properties of these tools, the research addresses a significant gap in the literature by providing evidence on their suitability for the region. Additionally, it highlights the urgent need for standardized validation methodologies to ensure consistency and reliability in the adaptation and application of HRQoL instruments across diverse Asian contexts. This will ultimately facilitate more robust research and clinical practice, enabling a better understanding of the quality of life of breast cancer patients in the region (Cardoso et al., 2018).

Based on the background above, the objective of this research is to evaluate the reliability and validity of health-related quality of life (HRQoL) measurement tools used for breast cancer patients in Asia. This research aims to identify the most appropriate measurement tools based on their psychometric properties and to develop recommendations for standardized validation methodologies that can be applied within the diverse cultural and linguistic contexts of Asia. The benefits of this research include making a significant contribution to the advancement of research and clinical practices in Asia. With reliable and valid HRQoL measurement tools, this research can assist healthcare professionals and researchers in understanding the holistic needs of breast cancer patients, enabling more targeted interventions. Furthermore, the findings of this research are expected to serve as a foundation for developing health policies and improving the quality of life of breast cancer patients in the region through a more standardized and culturally relevant approach.

METHOD

A thorough literature search was conducted by two independent reviewers using multiple electronic databases, including PubMed, ScienceDirect, and ProQuest, from inception until October 1st, 2024. The search terms included “Breast cancer,” “Breast neoplasm,” “Health-related Quality of Life,” “Validity,” “Reliability,” and “Asia,” which were adjusted as per the specific search criteria of each database. To address potential publication bias, strategies such as the use of funnel plots for visual assessment and sensitivity analyses to test the robustness of the findings were incorporated.

This review includes studies conducted in Asia that report the questionnaire for assessing the HRQoL of breast cancer patients. Studies were included if they: (1) focused on adult patients (≥18 years old) with newly diagnosed or followed-up breast cancer in Asian countries, (2) used HRQoL questionnaires as part of their assessment, (3) included psychometric evaluations such as Cronbach’s alpha, test-retest reliability, construct validity, or criterion validity, and (4) were observational studies (cross-sectional, cohort, or case-control) or validation studies. Only peer-reviewed publications that provide specific instruments for assessing HRQoL of breast cancer patients were included.

Data extraction from the included studies was carried out independently by two investigators. To enhance consistency among reviewers, a pilot phase was conducted using the first five studies. Any discrepancies during data extraction were resolved through consensus. Predefined forms were used to extract data into a spreadsheet program, capturing the following metrics: author and year, country, research design, number of patients, mean age, patient characteristics, instrument details, and psychometric outcomes, including reliability metrics (e.g., Cronbach’s alpha) and validity measures (e.g., construct or criterion validity). Funnel plots were generated to assess the symmetry of effect sizes, and sensitivity analyses were performed to determine the impact of excluding studies with high risk of bias or outliers on the overall conclusions (Afonso et al., 2024).

RESULT AND DISCUSSION

Literature Search and Characteristics of Included Studies

After conducting the author search on electronic databases using the specified search strategy, a total of 1342 studies were identified. Among these, 853 studies were duplicates, and an additional 237 studies were excluded after reviewing the titles and abstracts. Further exclusions were made based on availability and failure to meet the inclusion criteria (Maghfour et al., 2023). The search yielded in a final fifteen studies for qualitative analysis and five studies for quantitative synthesis (Figure 1). The five included studies were conducted in Kuwait, China, Iran, India, and Nepal, with sample sizes ranging from 50 to 348 patients. The average age of participants across studies ranged from 46.2 to 54.48 years. Most studies assessed breast cancer patients undergoing or following treatment using various HRQoL instruments, including EORTC QLQ-C30 and QLQ-BR-23 FACIT-Sp1217, and mMOS-SS20. The extracted data and characteristics of the included studies can be found in Table 2.

Risk of Bias in Included Studies

The summary from bias assessment were shown in Table 3 for all studies. In summary, we found that all studies included in this review resulted in a score of ≥7 which translated to good and very good quality in terms of AHRQ standards (Adam et al., 2019). Therefore, we conclude that all studies included in this review were of low risk of bias.

Reliability of HRQoL Instruments

The pooled Cronbach's alpha values of 0.871 (95% CI: [0.812 – 0.914]) demonstrated strong internal consistency for the instruments assessed (Figure 2). The EORTC QLQ-C30 showed a pooled Cronbach's alpha of 0.881 (95% CI: [0.773 – 0.942]), indicating excellent reliability. The QLQ-BR-23 also exhibited robust reliability, with a pooled Cronbach's alpha of 0.860 (95% CI: [0.770 – 0.919]). Similarly, the FACIT-Sp12 demonstrated robust reliability, with a pooled Cronbach's alpha of 0.87 (95% CI: [0.767 – 0.931]). The test for subgroup differences resulted in a p-value of 0.94, suggesting no significant differences in reliability across the subgroups analyzed. Heterogeneity across the studies for the EORTC QLQ-C30 and QLQ-BR-23 was deemed substantial, with an I^2 value of 93% and 90%, respectively.

Validity of HRQoL Instruments

Validity findings were inconsistently reported across the studies, limiting the ability to conduct a pooled analysis. Alawadi et al. (2019) noted that the QLQ-BR23 had superior item discriminant validity compared to the QLQ-C30, distinguishing effectively between patients with different disease stages and health statuses. Huang et al. (2025) provided strong evidence of construct validity for the EORTC QLQ-C30, reporting a content validity index (CVI) of 0.98, which supports the adequacy of the instrument in capturing HRQoL domains relevant to breast cancer patients. Despite these findings, three studies failed to report any validity metrics, posing challenges to synthesizing comprehensive conclusions on validity.

While the reported results affirm the validity of these instruments for assessing HRQoL in breast cancer populations, the substantial heterogeneity in research designs and reporting emphasizes the need for more standardized validation protocols. Subgroup differences in validity outcomes could not be assessed due to inconsistent reporting, underscoring the importance of future studies adopting uniform methods to evaluate and report psychometric properties (Oszlánszky et al., 2024).

In our meta-analysis, the pooled Cronbach's alpha values revealed high internal consistency across the evaluated instruments. These values exceed the commonly accepted threshold of 0.7, indicating robust reliability for clinical and research applications. The highest Cronbach alpha achieved by EORTC QLQ-C30, in which has previously demonstrated high reliability in non-Asian populations, confirming its consistency across diverse settings. However, the heterogeneity in reliability estimates

was substantial. Factors contributing to this heterogeneity likely include differences in cultural contexts, patient demographics, and the clinical settings in which the instruments were deployed. These findings align with earlier literature that highlighted variability in subscale performance, such as lower cognitive function reliability (Howlett et al., 2021).

Validity metrics were less consistently reported, but available data demonstrated the robustness of these instruments in specific domains. QLQ-BR23 exhibited superior item discriminant validity compared to QLQ-C30 in one research, reflecting its strength in breast cancer-specific assessments. Another research reported a content validity index of 0.98 for QLQ-C30, supporting its construct validity. These results align with global evidence showing significant correlations among subscales, reinforcing the tool's applicability across different cultural and clinical setting (Roberts et al., 2021). The variability in validity outcomes across studies limited the ability to conduct pooled analysis. This inconsistency underscores a broader challenge in HRQoL research—methodological differences in evaluating validity and the lack of standard reporting protocols. Future studies should incorporate standardized frameworks, such as the COSMIN guidelines, to ensure comprehensive validity assessments.

The comparison of reliability across the three instruments revealed no significant differences, with a subgroup analysis p-value of 0.94. This suggests comparable performance, supporting the interchangeable use of these instruments in assessing HRQoL in breast cancer patients. However, the high heterogeneity within individual instrument analyses warrants further investigation into context-specific factors influencing reliability and validity (Hebda-Boon et al., 2023).

Our review faced several limitations. The small number of included studies for certain instruments, such as FACIT-Sp12, precluded the assessment of heterogeneity and publication bias. The inconsistent reporting of validity metrics further restricted comprehensive meta-analyses. Additionally, the cultural diversity within Asia may contribute to variability, highlighting the importance of regional validation studies (Bergström et al., 2020).

Future studies should prioritize the use of standardized frameworks like COSMIN for reporting psychometric properties. Context-specific validation is crucial to address cultural and linguistic diversity in Asia. Longitudinal research is also needed to assess test-retest reliability and responsiveness over time. Collaborative efforts across institutions can enhance methodological consistency and generalizability, while exploring digital adaptations of HRQoL instruments may improve accessibility and data collection efficiency in resource-limited settings (Carter et al., 2021). By addressing these recommendations, future studies can refine HRQoL instruments and ensure their effective application in clinical and research settings across Asia, ultimately enhancing the assessment of breast cancer patients' well-being.

CONCLUSION

The results affirm the strong reliability of EORTC QLQ-C30, QLQ-BR23, and FACIT-Sp12 for HRQoL assessment in breast cancer patients in Asia, with validity outcomes providing additional support for their use. While subgroup differences were non-significant, the high heterogeneity underscores the need for standardized methodologies and reporting in future research. To strengthen the evidence base, further studies should consider longitudinal validation and the digitization of these instruments. Additionally, specific recommendations for their use should be developed to address diverse clinical and research needs, ensuring their effective application in oncology across various settings.

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