

Mapping the cancer-specific EORTC QLQ-BR53 onto the preference-based EQ-5D-5L instrument: A cross-sectional study in breast cancer in Vietnam

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ABSTRACT

Introduction: The EQ-5D instrument is highly recommended for health economic evaluations but is considered less practical than the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC) QLQ-BR53 in clinical studies with cancer patients. In these cases, cross-walking is recommended to convert the cancer-specific instrument onto the preference-based measures. This study aimed to develop an algorithm for direct mapping the QLQ-BR53 onto the EQ-5D-5L utility index in breast cancer patients. Methods: A cross-sectional study was conducted among patients diagnosed with HER2 breast cancer across six oncology hospitals in Vietnam from July to December 2020. Participants' health-related quality of life was assessed using QLQ-BR53 and EQ-5D. Two mapping algorithms - ordinary least squares (OLS) and generalized linear regression (GLM) - were compared. The best-fit model was selected based on MAE, RMSE, MAPE, and AIC. Internal validation was done using hold-out and cross-validation methods. Results: The study involved 338 participants with a mean age of 53.87 ± 9.97 years. Most were diagnosed early (55.7%) and non-metastatic (76.6%). The mean EQ-5D utility value was 0.863 ± 0.142 . The OLS model was the best fit for mapping EQ-5D utility scores from QLQ-BR53, with goodness-of-fit statistics: MAE = 0.786; RMSE = 0.1038; MAPE = 11.68%; and AIC = -524.2398. Key components included global health status, future perspective, pain, and arm symptoms. Conclusion: The developed model allows mapping QLQ-BR53 breast cancer data to EQ-5D-5L utility values, aiding in calculating quality-adjusted life years (QALYs) for cost-utility analyses in breast cancer.

Keywords: mapping, EQ-5D, QLQ-BR53, breast cancer

1. INTRODUCTION

Breast cancer is a disease in which cells grow rapidly and abnormally, forming a tumor and later on, metastasizing to other parts of the body [1]. It is the most prevalent cancer in women with more than 2.2 million new cases recorded in 2020 and is the cause of 685,000 deaths annually [2, 3]. In Vietnam, concerns have heightened following a notable increase in newly diagnosed cases, reaching 15,000 people in 2018, thereby imposing a significant societal burden [4]. Assessing the health-related quality-of-life (HRQoL) is crucial in treatment decision-making and health-economic analyses [5]. When evaluating the patients' HRQoL, disease-specific instruments are usually due to their sensitivity and relevance to the specific challenges faced by patients [6]. The QLQ-BR53, which

combines of QLQ-C30 and QLQ-BR23 questionnaires, is widely recognized as one of the primary HRQoL tools for breast cancer patients, developed by the European Organization for Research and Treatment of Cancer (EORTC) [7]. However, according to the National Institute for Health and Care Excellence (NICE), this instrument is less favored for cost-utility analyses. Instead, the preference-based EuroQoL-5D (EQ-5D) measure, which evaluates the generic HRQoL, is utilized for calculating of Quality-adjusted Life Year (QALY) [6]. To address the gap in preference-based utility indices without imposing additional assessment burdens on patients, this study aims to develop a mapping algorithm to convert the Vietnamese version of the QLQ-BR53 into the 5-level EQ-5D (EQ-5D-5L) utility score, specifically for the

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breast cancer patient population in Vietnam.

2. METHODS

2.1. Study design and population

A cross-sectional study was conducted from July to December 2020, involving breast cancer patients receiving treatment at six hospitals in Vietnam: Bach Mai Hospital, Cho Ray Hospital, Ho Chi Minh City Oncology Hospital, Da Nang Oncology Hospital, Vietnam National Cancer Hospital, and Ha Noi Oncology Hospital. Patients' information and HRQoL data were collected through a face-to-face interview using a self-developed form and two standardized questionnaires: the EQ-5D-5L and EORTC QLQ-BR53. Informed consent was obtained from all participants prior to their inclusion in the study.

Participants were included in the study if they met the following criteria: (1) a confirmed diagnosis of breast cancer, (2) no indication of mental disorder, (3) the ability to fully comprehend and respond to the interviewer's questions, and (4) consent to participate in the research. Individuals who lacked basic socio-demographic information, or had incomplete survey or clinical data, were excluded from the study.

2.2. Instruments

EQ-5D-5L is a set of questions investigating 5 aspects: mobility, self-care, usual activities, pain/discomfort, and anxiety/distress. Each aspect is evaluated through a multiple-choice question based on patients' current condition. Respondents are asked to self-rate their capability to perform the aforementioned activities on a scale of 5, from "No problem" to "Extreme problem". By that, participants' health states are converted into utility scores using the countries' specified value sets[8].

EORTC QLQ-BR53 is a composite scale combining the QLQ-C30 and QLQ-BR23 instrument. The QLQ-C30 assesses the health conditions of patients diagnosed with various types of carcinoma, while the QLQ-BR23 is specifically designed for breast cancer patients. The QLQ-BR53 includes 23 items, grouped into three subscales: functioning, symptoms, and global health status. Each subscale is scored using distinct formulas, with scores ranging from 0 to 100. Higher scores in the functioning and global health status subscales indicate better health conditions, whereas higher scores on the symptom subscale reflect greater symptom severity.[9].

2.3. Statistical analysis

Patient's demographic and clinical characteristics were described using mean (\pm standard deviation) or percentage. The normality of variables was

assessed using Shapiro-Wilk test. The conceptual overlap between the source and output variable was evaluated through Spearman's rank correlation.

2.3.1. Modelling approaches

Ordinary least square (OLS) estimates the unknown parameters by constructing a linear function based on the least square principle, which involves minimizing the sum of squared errors between the observed independent and dependent variables. This method is the most widely used in mapping studies and has significantly contributed to the prediction of various researches[10]. OLS regression requires certain assumptions, including normality, collinearity, and homogeneity of variance, all of which can be examined by the respective tests. In addition to the OLS model, generalised linear model (GLM) is another commonly applied algorithm in cross-walking studies, as it relaxes some of the assumptions associated with OLS [11, 12]. Hence, this study evaluated the predictive accuracy of the two approaches (i.e. OLS and GLM) based on three model specifications:

- Model 1: QLQ-C30 + age
- Model 2: QLQ-BR23 + age
- Model 3: QLQ-BR53 + age

The inclusion of demographic characteristics, particularly age, in model specifications has been shown to enhance model performance in literature review [11].

2.3.2. Measures of model performance

Model performance was evaluated using two main criteria: mean absolute error (MAE) and root mean squared error (RMSE). Additionally, mean absolute percentage error (MAPE) and Akaike's information criteria (AIC) were considered. Lower values for these indicators indicate reduced error in the regression model, reflecting improved predictive ability.

Two internal validation techniques were employed. In the first validation procedure (Validation I), a hold-out subsample of 170 subjects was randomly selected to assess the mapping function. In the second validation procedure (Validation II), the cohort was arbitrarily divided into two subsets. with 80% of the sample used for model construction (training data) and the remaining 20% utilized to validate the accuracy of the same model (validation data). All analyses were conducted using R version 4.5.0, with statistical significance set at $p < 0.05$.

3. RESULTS AND DISCUSSION

3.1. Sample characteristics

The study interviewed 371 patients and eliminated

34 unqualified responses based on the selecting criteria. This resulted in 338 eligible responses, with demographic and clinical characteristics analyzed as detailed in Table 1. All the participants were female, with ages ranging from 28 to 84 years (mean age: 53.87 ± 9.97). The majority resided in urban areas (71.6%), compared to 26.0% living in rural settings. More than half of the sample was in the early stages

of breast cancer (55.7%), while metastatic patients accounted for less than 10%. The medical records indicated that 90.0% of the patients had undergone surgical procedures, and one-third of the participants (35.2%) were receiving radiotherapy. Most patients were prescribed with the combination regimens of targeted therapy and chemotherapy (71.0%) in comparison with the monotherapies.

Table 1. Demographic characteristics (n = 338)

Characteristics	Value
Mean age (± SD)	53.87 (± 9.97)
Hospital	
Bach Mai Hospital	12 (3.6%)
Ha Noi Oncology Hospital	18 (5.3%)
Da Nang Oncology Hospital	13 (3.8%)
Ho Chi Minh City Oncology Hospital	143 (42.3%)
Cho Ray Hospital	30 (8.9%)
Vietnam National Cancer Hospital	122 (36.1%)
Academic level	
Not graduated from high school	128 (37.9%)
High school graduate	76 (22.5%)
Vocational/College diploma	30 (8.9%)
Bachelor’s degree	94 (27.8%)
Postgraduate degree	10 (3.0%)
Gender	
Female	338 (100.0%)
Place of residence	
Urban	242 (71.6%)
Rural	88 (26.0%)
Other	8 (2.4%)
TNM stages	
Stage I	36 (10.7%)
Stage II	152 (45.0%)
Stage III	83 (24.6%)
Stage IV	26 (7.7%)
Unknown	41 (12.1%)
Metastatic status	
Nonmetastasized	259 (76.6%)
Metastasized	24 (7.1%)
Unknown	29 (16.3%)
History of surgery	
No	44 (13.0%)
Yes	294 (87.0%)
History of radiotherapy	
No	219 (64.8%)
Yes	119 (35.2%)
Type of treatment	
Targeted therapy	85 (25.1%)
Chemotherapy	13 (3.8%)
Combination	240 (71.0%)

3.2. Quality-of-life descriptive statistics

Figure 1 presents the EQ-5D utility score based on the Vietnamese value set, which exhibited a

significant rightward skew. The average utility score was 0.863 ± 0.142, with a range from 0.105 to 1.000. Approximately 30% of the participants obtained full

health with the health utility value of 1.000.

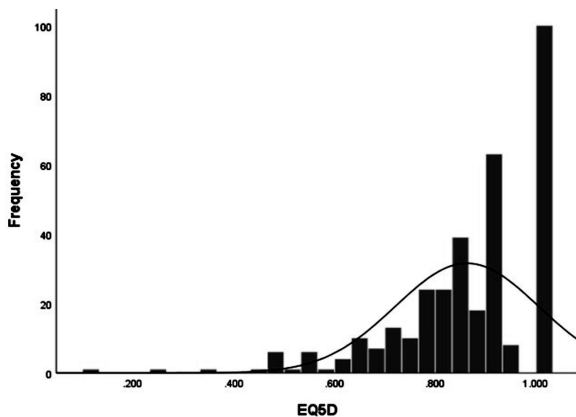


Figure 1. Histogram of EQ-5D score

Table 2 demonstrates the HRQoL of breast cancer patients using the QLQ-BR53 questionnaire. The global health status, reflecting patients' conditions over the past four weeks, was reported at a moderate level of 60.11 ± 15.80 . Among the nine dimensions of the functioning scale, aspects related to sexual activities- specifically sexual functioning and sexual enjoyment-received notably high scores (89.10 ± 16.85 and 80.54 ± 19.56 , respectively), despite a low response rate. Conversely, social functioning was the lowest, with a score of 66.27 ± 27.44 . Regarding potential symptoms experienced during treatment, insomnia and financial struggles were highlighted as the most significant concerns, with scores of 37.77 ± 30.11 and 55.82 ± 32.69 , respectively.

Table 2. HRQoL descriptive statistics

Variable	Response rate (%)	Mean (\pm SD)	Range
EORTC QLQ-C30			
Physical functioning (PF)	100.0	75.35 (17.75)	20.0 – 100.0
Role functioning (RF)	100.0	70.12 (27.20)	0 – 100.0
Cognitive functioning (CF)	100.0	74.11 (22.92)	0 – 100.0
Emotion functioning (EF)	100.0	77.79 (21.54)	16.67 – 100.0
Social functioning (SF)	100.0	66.27 (27.44)	0 – 100.0
Dyspnea (DY)	100.0	14.20 (21.53)	0 – 100.0
Pain (PA)	100.0	27.61 (22.46)	0 – 100.0
Fatigue (FA)	100.0	30.37 (23.54)	0 – 100.0
Insomnia (SL)	100.0	37.77 (30.11)	0 – 100.0
Appetite loss (AP)	100.0	29.39 (32.55)	0 – 100.0
Nausea and vomiting (NV)	100.0	8.93 (17.51)	0 – 100.0
Constipation (CO)	100.0	11.64 (20.93)	0 – 100.0
Diarrhea (DI)	100.0	10.36 (19.76)	0 – 100.0
Financial struggle (FI)	100.0	55.82 (32.69)	0 – 100.0
Global health status (GH)	100.0	60.11 (15.80)	8.33 – 100.0
EORTC QLQ-BR23			
Systemic therapy side-effects (ST)	100.0	29.73 (17.78)	0 - 80.95
Breast symptoms (BS)	100.0	20.05 (18.37)	0 - 100.0
Arm symptoms (AS)	100.0	14.40 (14.20)	0 - 66.67
Upset by hair loss (HL)	47.63	44.75 (35.93)	0 - 100.0
Body image (BI)	100.0	70.76 (27.85)	0 - 100.0
Future perspective (FU)	100.0	52.56 (32.20)	0 - 100.0
Sexual functioning (SEF)	100.0	89.10 (16.85)	33.33 - 100.0
Sexual enjoyment (SEE)	64.79	80.54 (19.56)	0 - 100.0

3.3. Mapping QLQ-BR53 onto EQ-5D

3.3.1. Conceptual overlap

Due to the relatively low response rate in “Sexual enjoyment” and “Upset by hair loss” (64.79%; 47.63%, respectively), the researchers excluded these two dimensions to minimize instability in model estimation. The conceptual overlap between

the QLQ-BR53 and EQ-5D was examined using Spearman's rank correlation test, as detailed in Table 3 It was observed that most correlation coefficients fell within the absolute range of 0.005 to 0.509, indicating weak to moderate relationships between the dimensions of both the source and target measures.

Table 3. Spearman rank correlation of QLQ-BR53 dimensions and EQ-5D utility scores

	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety/depression
Physical functioning	-0.421**	-0.252**	-0.319**	-0.276**	-0.128**

	Mobility	Self-care	Uuasl activities	Pain/discomfort	Anxiety/depression
Role functioning	-0.191**	-0.153*	-0.331**	-0.285**	-0.187**
Cognitive functioning	-0.161**	-0.103	-0.176**	-0.221**	-0.228**
Emotional functioning	-0.102	-0.066	-0.068	-0.273**	-0.504**
Social functioning	-0.231**	-0.159**	-0.310**	-0.239**	-0.309**
Dyspnea	0.163**	0.160**	0.181**	0.186**	0.144**
Pain	0.251**	0.141**	0.289**	0.459**	0.189**
Fatigue	0.400**	0.236**	0.425**	0.391**	0.322**
Insomnia	0.130*	0.157**	0.158**	0.249**	0.235**
Appetite loss	0.258**	0.186**	0.269**	0.224**	0.206**
Nausea and vomiting	0.175**	0.109**	0.061	0.203**	0.147**
Constipation	0.157**	0.034	0.109*	0.139*	0.133*
Diarrhea	0.131*	0.133*	0.126*	0.224**	0.132**
Financial struggle	0.101	0.081	0.125*	0.143**	0.231**
Global health status	-0.369**	-0.210**	-0.372**	-0.271**	-0.315**
Systemic therapy side effects	0.289**	0.185**	0.236**	0.302**	0.343**
Arm symptoms	0.292**	0.159**	0.217**	0.377**	0.186**
Breast symptoms	0.102	0.045	0.063	0.315**	0.152**
Body image	-0.118**	-0.005	0.034	-0.188**	-0.424**
Future perspective	-0.108*	-0.136*	-0.076	-0.144**	-0.490**
Sexual functioning	0.159**	0.152**	0.124*	-0.058	0.053

* statistically significant at the 0.05 level

3.3.2. Model performance

Goodness-of-fit statistical analyses are summarized in Table 4 and 5. It is evident that OLS 3, which incorporated all 23 dimensions of the QLQ-BR53 questionnaire, demonstrated the best performance among the six models evaluated. In the random population (Validation I), OLS 3 yielded the lowest

values for MAE (0.079), RMSE (0.105), MAPE (12.16%), and AIC (-237.005). Similar results were observed in full-sample analysis, with MAE of 0.079, RMSE of 0.104, MAPE of 11.37% and AIC of -524.240. These findings suggest that OLS model 3 provided superior predictions of utility scores relative to the observed values.

Table 4. Goodness-of-fit results from validation samples

	Validation I (n = 170)					Validation II (cross validation)			
	Mean	MAE	RMSE	MAPE	AIC	Mean	MAE	RMSE	MAPE
Observed EQ-5D	0.859	-	-	-	-	0.859	-	-	-
OLS 1	0.859	0.081	0.110	12.62%	-232.715	0.879	0.085	0.125	13.50%
OLS 2	0.859	0.091	0.121	14.59%	-218.025	0.876	0.087	0.118	13.20%
OLS 3	0.859	0.079	0.105	12.16%	-237.005	0.880	0.081	0.120	12.94%
GLM 1	0.860	0.084	0.113	12.98%	-134.759	0.878	0.085	0.128	10.41%
GLM 2	0.859	0.091	0.122	14.67%	-128.663	0.877	0.087	0.119	10.39%
GLM 3	0.860	0.084	0.109	12.65%	-133.653	0.880	0.086	0.124	10.17%

OLS: ordinary least square, GLM: generalised linear model, model 1: QLQ-C30 + age (15 variables), model 2: QLQ-BR23 + age (7 variables), model 3: QLQ-BR53 + age (22 variables)

Table 5. Goodness-of-fit results from full sample

	Full sample (n = 338)				
	Mean	MAE	RMSE	MAPE	AIC
Observed EQ-5D	0.863	-	-	-	-
OLS 1	0.863	0.081	0.109	11.87%	-505.901
OLS 2	0.863	0.089	0.116	13.04%	-477.295
OLS 3	0.863	0.079	0.104	11.37%	-524.240

	Full sample (n = 338)				
	Mean	MAE	RMSE	MAPE	AIC
GLM 1	0.863	0.083	0.110	12.11%	-353.749
GLM 2	0.863	0.090	0.118	13.16%	-339.942
GLM 3	0.863	0.081	0.106	11.68%	-365.327

OLS: ordinary least square, GLM: generalised linear model, model 1: QLQ-C30 + age (15 variables), model 2: QLQ-BR23 + age (7 variables), model 3: QLQ-BR53 + age (22 variables).

3.3.3. Optimal mapping function

Regression analysis was performed based on the best fitting model specification – OLS 3. Table 6 presents the coefficients of the mapping algorithm. Four scales of the QLQ-BR53 were found to be statistically significant ($p < 0.05$): fatigue

($\beta = -0.0013$), global health status ($\beta = 0.0010$), future perspective ($\beta = 0.0008$), and arm symptoms ($\beta = -0.0010$). Therefore, the EQ-5D utility score can be predicted using the following follows: EQ-5D utility score = $0.7001 - 0.0013 \times FA + 0.0010 \times GH + 0.0008 \times FU - 0.0010 \times AS$

Table 6. Coefficients of mapping algorithm

	Coefficient	SD
Constant	0.7001*	0.0902
Age	0.0001	0.0007
Physical functioning	0.0010	0.0006
Role functioning	0.0003	0.0003
Social functioning	0.0003	0.0003
Emotional functioning	0.0007	0.0004
Cognitive functioning	-0.0004	0.0004
Pain	-0.0003	0.0004
Fatigue	-0.0013*	-0.0005
Diarrhea	-0.0003	0.0003
Dyspnea	0.0001	0.0003
Constipation	-0.0001	0.0003
Insomnia	-0.00002	0.0002
Appetite loss	0.0002	0.0002
Nausea and vomiting	-0.0002	0.0005
Financial struggle	0.0002	0.0002
Global health status	0,0010*	0,0005
Body image	0.0003	0.0002
Future perspective	0,0008*	0,0002
Sexual functioning	-0.0004	0.0004
Systemic therapy side effects	-0.0005	0.0006
Arm symptoms	-0,0010*	0,0005
Breast symptoms	-0.0003	-0.0005

* statistically significant at the 0.05 level

4. DISCUSSION

The HRQoL measurement and valuation are essential components of economic evaluation. According to NICE's pharmacoeconomics guideline, EQ-5D is the preferred measure of HRQoL for adults, serving as the basic for calculating QALY in cost-utility analyses. the EQ-5D is often less favored than the QLQ-BR53 in specific contexts To address this limitation, mapping methods have been introduced to convert QLQ-BR53 scores into EQ-5D utilities. This study represents the first mapping effort utilizing the Vietnamese version

of the EORTC QLQ-BR53 specifically for breast cancer patients, with the EQ-5D-5L utility score calculated using the Vietnamese value set. The findings are thus tailored to the Vietnamese population, enhancing applicability compared to prior research conducted in other regions.

Based on the optimal goodness-of-fit indicators - MAE, RMSE, MAPE and AIC - OLS 3, which constructed a linear regression equation using the QLQ-BR53 dimensions, demonstrated superior

predictive capability among the six models evaluated (MAE = 0.786; RMSE = 0.1038; MAPE = 11.68%; AIC = -524.2398). In fact, OLS was the most prevalent method in cross-walking studies, as reported in the literature reviews [10, 13]. However, this does not imply that OLS is the most appropriate method to apply [14].

The combination of 2 questionnaires - QLQ-C30 and QLQ-BR23 - enhanced predictive accuracy, corroborating findings from Liu et al [15]. This improvement likely stems from the combined questionnaire's inclusion of more variables, which strengthens the correlation between the QLQ-BR53 and the EQ-5D index. Significant explanatory variables in the mapping algorithm included global health status, future perspective, fatigue, and arm symptoms, with coefficients aligning logically with the understanding that better functioning and reduced symptom severity correspond to improved health states and higher utility scores.

This study has several limitations. Although it is a multi-center study that recruited a diverse patient cohort from various regions in Vietnam, the focus on the HER2+ subtype may not fully represent the broader breast cancer population. As such, the mapping algorithm developed may have limited generalizability for breast cancer in Vietnam, warranting further research involving samples from other subtypes. Additionally, only in-sample validation techniques were employed; external validation should be conducted to better assess how well the model can be expected to perform in real-world settings.

5. CONCLUSIONS

In conclusion, the algorithm developed in this study enables the calculation of quality-adjusted life years (QALYs) in breast cancer cost-utility analyses using EORTC QLQ-BR53 data, thereby reducing the respondent burden for both researchers and patients.

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Ánh xạ bảng câu hỏi EORTC QLQ-BR53 về ung thư lên bảng câu hỏi EQ-5D-5L: Một nghiên cứu cắt ngang về ung thư vú tại Việt Nam

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TÓM TẮT

Giới thiệu: Công cụ EQ-5D được khuyến nghị cao trong các đánh giá kinh tế y tế nhưng được cho là kém thực tiễn hơn so với Bảng câu hỏi chất lượng cuộc sống của Tổ chức Nghiên cứu và điều trị Ung thư châu Âu (EORTC) QLQ-BR53 trong các nghiên cứu lâm sàng trên bệnh nhân ung thư. Trong những trường hợp này, phương pháp chuyển đổi được khuyến khích để chuyển đổi các công cụ chuyên biệt về ung thư thành các thang đo dựa trên sở thích. Nghiên cứu này nhằm phát triển một thuật toán để ánh xạ trực tiếp QLQ-BR53 sang chỉ số tiện ích EQ-5D-5L ở bệnh nhân ung thư vú. **Phương pháp:** Một nghiên cứu cắt ngang được thực hiện trên bệnh nhân ung thư vú HER2 tại 6 bệnh viện chuyên khoa ung bướu ở Việt Nam từ tháng 7 đến tháng 12 năm 2020. Chất lượng cuộc sống liên quan đến sức khỏe của bệnh nhân được đánh giá bằng QLQ-BR53 và EQ-5D. Hai thuật toán ánh xạ hồi quy bội tuyến tính thường (OLS) và hồi quy tuyến tính tổng quát (GLM) được so sánh. Mô hình phù hợp nhất được lựa chọn dựa trên các chỉ số MAE, RMSE, MAPE và AIC. Việc xác nhận nội bộ được thực hiện bằng phương pháp giữ lại và kiểm định chéo. **Kết quả:** Nghiên cứu bao gồm 338 bệnh nhân với độ tuổi trung bình là 53.87 ± 9.97 tuổi. Đa số bệnh nhân được chẩn đoán ở giai đoạn sớm (55.7%) và không có di căn (76.6%). Giá trị tiện ích trung bình của EQ-5D là 0.863 ± 0.142 . Mô hình OLS phù hợp nhất để ánh xạ điểm tiện ích EQ-5D từ QLQ-BR53, với các chỉ số độ phù hợp: MAE = 0.786; RMSE = 0,1038; MAPE = 11.68%; và AIC = -524,2398. Các thành phần chính bao gồm tình trạng sức khỏe toàn cầu, triển vọng tương lai, đau và triệu chứng cánh tay. **Kết luận:** Mô hình được phát triển cho phép ánh xạ dữ liệu QLQ-BR53 của bệnh nhân ung thư vú sang giá trị tiện ích EQ-5D-5L, hỗ trợ trong việc tính toán năm sống điều chỉnh theo chất lượng (QALYs) cho các phân tích chi phí - hiệu quả trong ung thư vú.

Từ khóa: ánh xạ, EQ-5D, QLQ-BR53, ung thư vú

Received: 25/09/2024

Revised: 16/10/2024

Accepted for publication: 16/10/2024