

## Evaluation Of The Tools Used To Assess The Quality Of Life In Breast Cancer Survivors: A Narrative Review

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### ABSTRACT

Cancer is a disease that can originate in almost any tissue or organ of the body when abnormal cells proliferate uncontrollably, invading neighboring tissues or organs, and spread to other parts of the body. The most prevalent cancer in the world is breast cancer (BC). The disease itself affects patients' physical and emotional health, as well as their families, social lives, and employment. Additionally, BC treatments like surgery, chemotherapy, radiotherapy, and hormone therapy can have severe side effects on patients. This complex phenomenon impacts the quality of life (QOL) of BC patients negatively. This review is aimed at identifying the pragmatic and valid clinical tool to determine the health-related quality of life (HRQOL) in females with BC. A comprehensive search was conducted in Google Scholar, Cochrane, EbscoHost, MEDLINE, PubMed, EMBASE, CENTRAL, CINAHL, and the Physiotherapy Evidence Database from inception to December 2024. The total number of screened articles were 46, out of which 39 articles provided relevant data on the QOL of BC patients. The reviewed articles included those that focused on populations of BC patients whose QOL was affected by either the treatment interventions or the disease itself. The results from these articles suggest an overall reduction in the scores on the functional scales of the questionnaires, whereas an increase in the scores on the symptom scale is exhibited, both indicating a poor QOL as the stage of the disease progresses. After reviewing the articles, it was determined that each of these studies used either C30 or BR23, or both, to compare the various QOL domains in BC patients, validating its efficacy. The EORTC questionnaires are therefore the most valid and reliable instruments for assessing the QOL in patients with BC.

**Keywords:** Breast cancer, EORTC, Health related quality of life, Chemotherapy.

**How to Cite:** Mudasir Rashid Baba, Negar Shafiei Sabet, Saeid Reza Doustjalali, Chan Sook Chin, Khin Thane Oo, Mon Mon Thawda Oo, Ohnmar Lwin, Su Wai Wai Lwin, Sahar Zaidi, Habiba Sundus, Muhammad Parial Shahani, Shahnaz Haque, Noraasyikin Ramli, Mohd Zin Bidin, Swe Swe Latt, Myat Myo Naing, Leela Anthony, Aye Aye Tun, Maheswaran Solayappan, Jegathambigai RN, Sutha Devaraj, Sergey Gupalo and Nazmul MHM., (2025) Evaluation Of The Tools Used To Assess The Quality Of Life In Breast Cancer Survivors: A Narrative Review, *Journal of Carcinogenesis*, Vol.24, No.2s, 1093-1108

## 1. INTRODUCTION

Cancer is a large group of diseases that involve abnormal cell growth that can develop in any tissue or organ of the body and has the potential to infiltrate the usual boundaries between organ and body and/or spread to other organ<sup>1</sup>. In 2018, it was reported that around 9.6 million people died because of cancer which accounts for one in six deaths. Men are predisposed to developing lung, colorectal, prostate, liver, and stomach cancer, while in women breast, cervical, colorectal, lung, and thyroid cancer are more common<sup>2</sup>. Every year 2.1 million women are affected with BC, which is the most common and persistent of all cancers. BC was responsible for the deaths of 627,000 women in 2018, or about 15% of all cancer deaths among women. BC rates are rising in every region worldwide, not just in developed regions<sup>3</sup>. In 2018, there were 1,62,468 new cases of BC and 87,090 deaths among Indian women (Prusty et al., 2020) (Figure 1). Patient, their families, communities, and healthcare systems all suffer greatly as a result of cancer's immense physical, emotional, and financial burden<sup>2</sup>.

BC is potentially life-threatening, and can have dramatic effects on various aspects of a patient's life (Figure 2 & 3). The BC diagnosis itself can have a physical, emotional, and psychological effect on the patient and the family, which affects their social activities and work<sup>5</sup>. Cancer treatments like surgery, radiotherapy, chemotherapy, and hormone therapy each carry their own side effects, which add to the patient's problems and negatively impact their QOL<sup>6</sup>. The impact made throughout the period of diagnosis and treatment is tremendous and may continue for several years, thus it is considered a chronic condition. Studies prove that side effects like uncontrolled nausea, vomiting, hair loss, and weight gain have a negative effect on the health-Related Quality of Life (HRQOL) of women with BC who are receiving chemotherapy<sup>7</sup>.

QOL or HRQOL pertains to an "individual's perspective of their rank/value in life in cultural and value-based systems in which they live and in relation to their targets, expectations, and standards" and is impacted by a person's psychological state and physical health<sup>8</sup>. BC can be described as one of the prevailing chronic conditions that adversely affects the HRQOL of a patient<sup>9</sup>. This makes it important to assess the HRQOL of a BC patient. In clinical oncology trials, HRQOL assessment is considered a key component. Assessment of HRQOL in BC patients is crucial to knowing the clinical benefits of the treatment given. HRQOL data have been predictors of primary clinical outcomes in previous studies of advanced stage of BC<sup>10</sup>.

Thus, an appropriate, well-validated measure to assess HRQOL parameters is a mandatory requirement, when determining the outcome of different treatments used for BC patients, like therapeutic modalities and psychological interventions. Such measures provide useful information concerning treatment expenses and its benefits, and they guide the clinician with management decisions in terms of modifying the intervention.<sup>11</sup> There are various instruments and questionnaires available to assess QOL in BC patients. This article's prime objective is to determine the best questionnaire available to assess HRQOL in BC patients so that it can be used in daily practice. A recent study conducted by Maribel Salas reviewed the HRQOL measures in BC patients excluding surgically managed patients, this article aims to review HRQOL in BC patients including surgically managed patients<sup>12</sup>.

## 2. METHODS

### Data Source

A comprehensive systematic search of databases like Google Scholar, Cochrane, Ebsco Host, MEDLINE, PubMed, EMBASE, CENTRAL, CINAHL, and Physiotherapy Evidence Database was carried out and all the relevant articles from inception to 2024 were screened based on the eligibility criteria given below. The systematic review did not necessitate ethical approval. The Boolean operators ('AND' and 'OR') were used to combine key words such as 'assessment,' 'scale,' 'quality of life,' 'health-related quality of life,' and 'breast cancer.'

**Table 1:** MeSH terms in systematic search

Table 1 represents the keywords used and medical subject heading (MeSH) terms.

### ELIGIBILITY CRITERIA:

#### Inclusion Criteria:

Articles from inception to 2024.

All articles including systematic reviews, randomized control trials, prospective observational studies, case-control study, case report, case series.

Open access articles.

Articles which are available in English language.

#### Exclusion Criteria:

Articles in other languages, other than English

Studies those which are not available in full text.

### 3. METHODOLOGICAL QUALITY ASSESSMENT OF ARTICLES

Critical appraisal skills programme (CASP) checklist, was used to determine the methodological quality validity and study quality of the articles included in the review. Different appraisal checklist was used for various types of studies like cross sectional study, systematic review, randomized control trail. Ratings are made as 'yes,' 'no,' 'can't tell' for each domain of quality appraisal tools <sup>13</sup>.

### 4. RESULTS

The broad systematic literature search identified a total of 46 research articles based on the eligibility criteria and 39 articles were found relevant and were hence included in this review. The articles included systematic reviews, randomized control trials, prospective observational study, case report, case-control study and case series.

The extracted data related to scales used for assessment of HRQOL in BC patients was summarized as the following in table 2:

Details of publication: article's citation and publication year

Article type

Participant's characteristics: Cancer type

QOL outcome scale used by the article

Main findings of the article

The authors conducted a qualitative review using the retrieved data, condensing the characteristics of the articles they had included into a narrative synthesis in Table 2 and 3.

**Table 1: MeSH terms in systematic search**

MeSH terms related to assessment, tools	MeSH terms related to Quality of life	MeSH terms related to breast cancer
Assessment OR Scale OR tools OR Assess OR Evaluate	Health related quality of life OR HRQOL OR Quality of life	Breast carcinoma OR Breast cancer

**Table 2: Characteristics of reviewed articles**

<u>Author and Year</u>	<u>Type of article</u>	<u>Type of participants</u>	<u>QOL scale used</u>	<u>Main Findings</u>
<b>Francisco <i>et al.</i>, (2019)<sup>19</sup></b>	Cross sectional study	BC patients undergoing chemotherapy	EORTC QLQ-C30, QLQ BR23 and HADSD	Depressive symptoms in BC patients receiving chemotherapy and monoclonal antibodies reduce various aspects of QOL.
<b>Anissa <i>et al.</i>, (2019)<sup>31</sup></b>	Cross sectional study	BC patients undergoing chemotherapy	EORTC QLQ-C30 and EORTC QLQ-BR23	BC chemotherapy patients' QOL is lower than the reference data and international findings.
<b>Kshirsagar <i>et al.</i>, (2019)<sup>20</sup></b>	Cross sectional study	BC surgery patients undergoing chemotherapy	EORTC BR-23 and EORTC C30	For the C-30 and BR23 questionnaires, various QOL domains were affected, with self-body image, sexual dysfunction, and anxiety caused by hair loss affecting the most.
<b>Rhythm <i>et al.</i>, (2019)<sup>16</sup></b>	Cross sectional study	BC patients undergoing	EORTC BR-23 and EORTC C30	Except for sexual functioning scores, BC patients receiving

		hormonal therapy		hormonal therapy had better QOL across all domains.
<b>Kamiska <i>et al.</i>, (2015)</b> <sup>37</sup>	Cross sectional study	BC Post mastectomy	EORTC BR-23 and EORTC C30	The QOL was found to be significantly better for patients conservatively treated, compared to the patients who underwent mastectomy
<b>Mona <i>et al.</i>, (2018)</b> <sup>25</sup>	Cross sectional study	BC	EORTC BR-23 and EORTC C30	Patients undergoing breast conservative surgery had more favorable functional outcomes, (role functioning) while patients who underwent modified radical mastectomy had more intense arm symptoms.
<b>Munirah <i>et al.</i>, (2020)</b> <sup>26</sup>	Cross sectional study	BC patients	EORTC BR-23 and EORTC C30	Body image was not affected by BC surgery and chemotherapy had the highest side effect score
<b>Wallweiner <i>et al.</i>, (2016)</b> <sup>28</sup>	Cross sectional study	BC patients	EORTC QLQ-BR23, EORTC QLQ-C30, EQ VAS and EQ-5D-5L	QOL and stress levels were shown with varying degrees of intensity and symptoms depending on the survey tool used.
<b>Dubashi <i>et al.</i>, (2010)</b> <sup>45</sup>	Descriptive study	BC patients	EORTC BR-23 and EORTC C30	The overall QOL of young women with BC in a tertiary care centre was good except for sexual function.
<b>Sharma <i>et al.</i>, (2017)</b> <sup>39</sup>	Cross-sectional study	BC patients	EORTC BR-23 and EORTC C30	Age, disease status, and stage of disease at the last follow-up were the factors impacting QOL in BC patients.
<b>Damodar <i>et al.</i>, (2013)</b> <sup>38</sup>	Cross-sectional study	BC patients	EORTC BR-23 and EORTC C30	The QOL of BC patients was significantly affected in functional and symptom scales. There exists a strong correlation between the length of treatment and the QOL of BC patients.
<b>Imran <i>et al.</i>, (2019)</b> <sup>35</sup>	Cross sectional study	BC survivors	EORTC BR-23 and EORTC C30	The patients had better QOL with respect to overall global health status, symptom and functional scales
<b>Thi <i>et al.</i>, (2019)</b> <sup>32</sup>	Cross sectional study	BC patients	EORTC BR-23 and EORTC C30	The HRQOL of patients with BC had better QOL than the patients who died who were similar at baseline.
<b>Chen <i>et al.</i>, (2018)</b> <sup>22</sup>	Cross sectional study	BC patients	EORTC BR-23 and EORTC C30	The study came to the conclusion that the functional/symptom scale differed depending on the stage of cancer, while similar

				information regarding the HRQOL of BC patients was obtained from the BR23 and EORTC QLQ-C30.
<b>Juan Xia (2017)</b> <sup>40</sup>	Cross-sectional study	BC patients	EORTC C30 and EORTC BR-23	Higher functional scores were found for people who were more active with an optimistic attitude towards life.
<b>Fakir <i>et al.</i>, (2016)</b> <sup>10</sup>	Prospective study	BC patients	EORTC BR-23 and EORTC C30	QOL among women with BC in Morocco was found to be fair. Women with later-stage BC were less socially active as compared to women diagnosed with early-stage BC
<b>Konieczny <i>et al.</i>, (2019)</b> <sup>46</sup>	Cross sectional study	BC patients	EORTC BR-23, EORTC C30 and author's questionnaire	QOL of BC patients (poor financial status) deteriorated with worsening symptoms.
<b>Weruska <i>et al.</i>, (2017)</b> <sup>47</sup>	Cross sectional study	BC patients	EORTC BR-23, EORTC C30 and Karnofsky Performance Scale (KPS).	There was positive correlation between functional capacity and QOL. QOL was better for women without metastasis than those with loco regional and distant metastases
<b>Thais <i>et al.</i>, (2019)</b> <sup>48</sup>	Randomized control trial	BC	SF-36, EORTC QLQ-C30 & EORTC QLQ-BR23	The study demonstrated that exercise programs for older BC survivors receiving aromatase inhibitor therapy had high clinical relevance and potential benefits for enhancing QOL.
<b>Edib <i>et al.</i>, (2016)</b> <sup>23</sup>	Cross sectional study	BC	SCNS-SF34 and EORTC QLQ-C30	The psychological domain had the highest unmet needs for supportive care, followed by the physical domain. Early BC survivors with advanced stage diagnoses and greater physical and mental needs had poor QOL.
<b>Kim <i>et al.</i>, (2018)</b> <sup>17</sup>	Cross sectional study	BC patients	EORTC QLQ-C30	Better recovery and QOL were seen in the no-depression group as compared to the persistent depression group.
<b>Rey <i>et al.</i>, (2017)</b> <sup>34</sup>	Cross-sectional study	BC patients	EORTC QLQ-BR23, EORTC QLQ-C30, AND State Trait Anxiety Inventory (STAI) (for anxiety)	The dimensions of physical function and prospects improved while state and trait anxiety reduced after treatment
<b>Carolyn <i>et al.</i>, (2017)</b> <sup>49</sup>	Cross-sectional study	BC patients	EORTC QLQ-C30 and the Life Orientation	BC patients showed reduced QOL on most symptom and functioning scales. The

			Test (LOT-R)	findings suggest that optimistic patients can deal better with the disease.
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**Table 3: Characteristics of reviewed articles**

<u>Author and Year</u>	<u>Type of article</u>	<u>Type of participants</u>	<u>QOL scale used</u>	<u>Main Findings</u>
<b>Jankowska <i>et al.</i>, (2020)</b> <sup>24</sup>	Cross-sectional study	BC	Acceptance of Illness Scale (AIS), EORT QLQ-C30 and the EORTC QLQ- BR23	There was a direct correlation and a positive correlation between illness acceptance and overall QOL.
<b>Abebe <i>et al.</i>, (2020)</b> <sup>29</sup>	Cross sectional study	BC	EORTC QLQ- C30 and EORTC QLQ- BR23	Poor QOL was seen in BC patients who underwent mastectomy when compared to international findings.
<b>Zheng <i>et al.</i>, (2016)</b> <sup>30</sup>	Cross sectional study	BC	EORTC QLQ- C30 and EORTC QLQ- BR23	Diabetes was associated with reduced QOL in BC survivors.
<b>Johannes <i>et al.</i>, (2016)</b> <sup>18</sup>	Cross sectional study	BC	EORTC QLQ- C30	The QLQ-C30 scales revealed good diagnostic accuracy in identifying patients who reported burden, restrictions, and/or a need for assistance with Emotional Function, Physical Function, Pain, and Fatigue.
<b>Nolte <i>et al.</i>, (2018)</b> <sup>44</sup>	Survey study	BC patients	EORTC QLQ- C30	The questionnaire can be used to compare HRQOL in cancer patients.
<b>Wallweiner <i>et al.</i>, (2017)</b> <sup>26</sup>	Prospective randomized controlled trial	BC patients	EORTC QLQ- C30 (e-PRO version)EORTC	The study concluded that there was a high correlation between paper based and electronic based version of the questionnaire and was proved reliable to use.
<b>Nagrani <i>et al.</i>, (2014)</b> <sup>15</sup>	Descriptive and analytical study	BC	EORTC QLQ- C30 & QLQ- BR23	A rural lifestyle is protective and reduces the risk of BC
<b>Li <i>et al.</i> (2022)</b> <sup>50</sup>	Cross sectional study	BC undergoing chemotherapy	Needs Self-Rating Questionnaire for BC and 36- item Short- Form Health Survey V. 2.0	Greater perceived needs satisfaction was linked to a higher QOL.
<b>Hanson <i>et al.</i> (2022)</b> <sup>41</sup>	Methodological study	BC	BREAST-Q	In the domains of psychosocial and sexual well-being, breast conserving surgery with radiation therapy patients had clinical improvements than patients with mastectomy and reconstruction without radiation therapy.



<b>Aune et al. (2022)</b> <sup>51</sup>	Systematic review and meta-analysis	BC	EORTC-C30, Functional Assessment of BC Therapy, and Functional Assessment of Cancer Therapy in General	HRQOL is improved in BC survivors by physical activity. The outcome was detrimental to physical, mental, and emotional well-being.
<b>Mai et al. (2022)</b> <sup>32</sup>	Prospective study	BC postoperative	EORTC QLQ-C30, QLQ-BR23, and EuroQoL-5D	HRQOL reduced during the treatment but improved gradually in 3 years follow-up and over the 15-years showed good improvement in QOL
<b>Sloniewski et al. (2022)</b> <sup>52</sup>	Cross sectional study	Breast and ovarian cancer	QLQ-C30, QLQ-BR23 and QLQ-OV28	Patients with BC had better health and QOL than those with ovarian cancer.
<b>Tsui et al. (2022)</b> <sup>42</sup>	Methodological study	BC	Breast utility instrument	The ten-dimensional final model was developed with a reliability of 0.86
<b>Meilani, Zanudin, and Mohd Nordin (2022)</b> <sup>43</sup>	Systematic review	BC related lymphedema		Lymph-ICF-UL was found to be the most suitable with high-quality evidence ratings and good overall psychometric properties
<b>Salas et al. (2022)</b> <sup>12</sup>	Systematic review	BC		EORTC C30 and FACT-B are reliable and valid tools for measuring HRQOL in BC patients.

**Table 4: Comparison of the tools used for assessing HRQOL in BC**

<u>Scale</u>	<u>No. of items</u>	<u>Characteristics</u>	<u>Reliability and validity</u>	<u>Population</u>	<u>Dimension</u>
EORTC QLQ- C30 <sup>53</sup>	30	It is a multi-item scale used to assess QoL in cancer patients in the past week	Internal consistency ranged from 0.72 to 0.86 Content validity established	All types of Cancer patients	Global health status, functional and symptom domains
EORTC OLQ- BR23 <sup>53</sup>	23	It assesses HRQOL in BC patients with respect to their health in the last week	Internal consistency is 0.78 to 0.83. Validity established	BC	Functional and symptom scale
EORTC OLQ- C30 (E-PRO VERSION) <sup>26</sup>	30	E-PRO is a digital application version of EORTC-C30 which measures QOL of cancer patients via digital means	High correlations in parallel forms reliability and internal consistency	Cancer patients	Global health status, functional and symptom domains
Acceptance of Illness Scale (AIS) <sup>54</sup>	8	It measures the level of acceptance and compliance to medical	Internal consistency is 0.82	Chronic illness-proved in cancer	Mental domain

		recommendations by a patient for a chronic illness		patients	
Life Orientation Test (LOT-R) <sup>55</sup>	10	It assesses one's level of optimism and can help to provide appropriate intervention by analysing one's harmful thought patterns	Internal consistency is 0.76. Convergent and discriminant validity is established	All conditions	Psychological
SF-36 <sup>56</sup>	36	Assesses HRQOL irrespective of disease.	Internal consistency is more than 0.85 Construct validity established.	All conditions	Physical functioning, Mental health
Karnofsky Performance Scale (KPS) <sup>57</sup>	10	Classifies patients according to their functional impairment	Internal reliability is 0.72	Cancer patients	Functional dimension
EQ-5D-5L <sup>58</sup>	5	It is a self-assessed HRQOL questionnaire	Internal consistency is greater than 0.7 Content and construct validity established	All conditions	Mobility, usual activities, pain/discomfort, self-care and anxiety/depression.
EQ VAS <sup>59</sup>	1	It is a self-reported health scale on a 100-point visual analogue scale.	Inconsistent construct validity and responsiveness. Sufficient construct validity	All conditions	Health status
BREAST-Q <sup>60</sup>	6 domains	It is a patient-reported outcome measure used in breast reconstruction surgery.	Internal consistency is 0.81 to 0.96. Content validity established	BC	Psychosocial, physical, and sexual well-being, satisfaction with breasts, overall outcome, and care process
Functional Assessment of Cancer Therapy-Breast <sup>61</sup>	37	Self-reported outcome measure specific to BC patients.	Internal consistency is 0.9. Convergent and divergent validity established	BC	A breast-cancer subscale, satisfaction with breasts, overall outcome, care process, psychosocial, physical, social, emotional, and functional well-being
Functional Assessment of Cancer Therapy-General <sup>62</sup>	27	Assesses HRQOL across 4 domains in cancer patients	Internal consistency is 0.9. Validity established.	Cancer patients	Physical, emotional, social and functional well-being
Breast utility instrument <sup>42</sup>	10	It is a BC preference-based instrument measuring HRQOL	Internal consistency is 0.86.	BC	Physical, emotional, social and symptom domains
Lymph- ICF-	29	It assesses	Internal consistency is	BC related	Mental function,



UL <sup>43</sup>		impairments in BC patients' post-surgery, lymphedema	0.72 to 0.98 Construct validity and responsiveness established	lymphedema	mobility, life, household activities and social activities, and physical function
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Figure 1: Graphical Representation of Breast Cancer Cases and Deaths

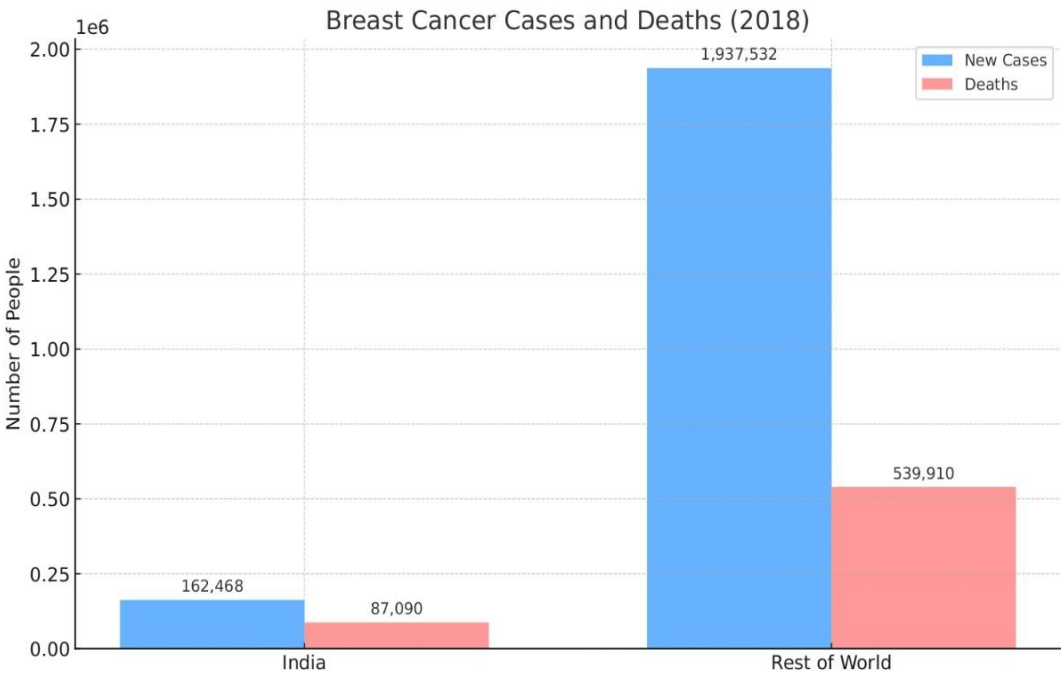
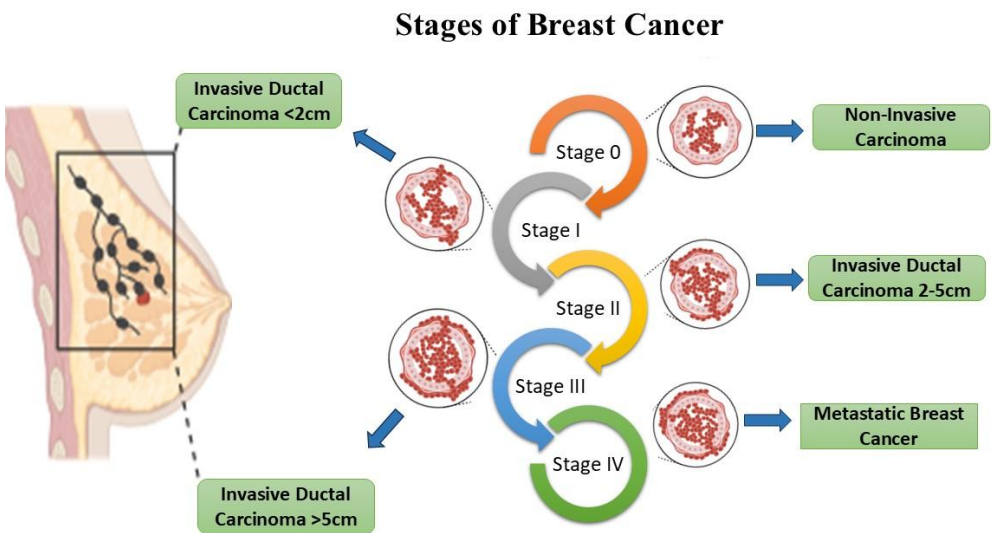
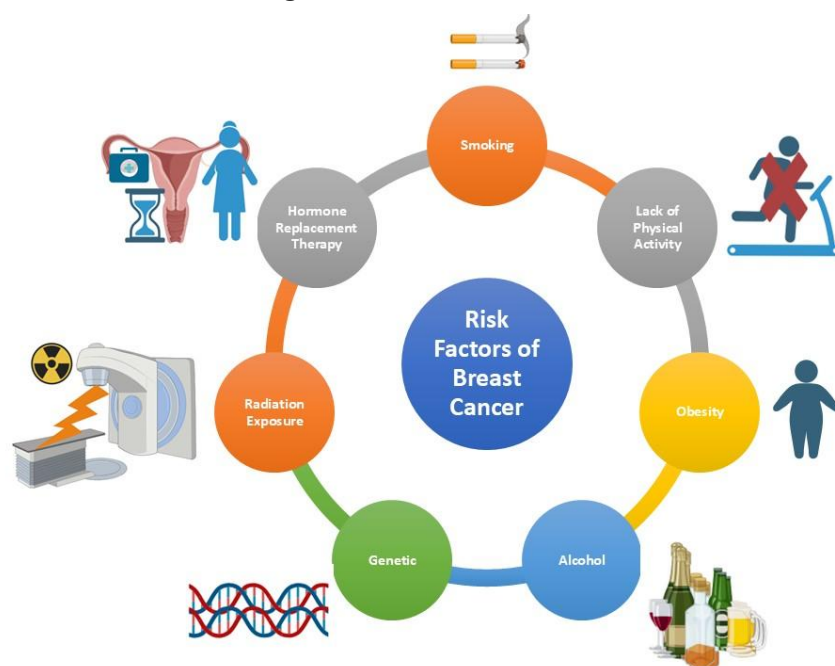


Figure 2: Stages of Breast Cancer



**Figure 3: Risk Factors of Breast Cancer**



**Figure 4: Quality of life in Breast Cancer Patients**



### Clinical evaluation questionnaire used for HRQOL in BC patients

The systematic review revealed that there are mainly 2 scales that are most used to evaluate the HRQOL in patients with BC. They are the European Organization for Research and Treatment for Cancer QOL Questionnaire-Core 30 (EORTC QLQ-C30) (Appendix 1) and EORTC QLQ-BR23 (Appendix 2) respectively.

### The EORTC QLQ-C30

The EORTC QLQ-C30 consists of three scales that correspond to the patient's previous week's condition. The Global Health Scale is the first. The Functional Scale is the second, with five domains: cognitive, emotional, social, and physical aspects of role-playing. Next is the Symptom Scale, which includes dyspnea, loss of appetite, sleep disorders, constipation, diarrhoea, and financial difficulties, in addition to three domains (pain, fatigue, and nausea and vomiting). A higher QOL or overall functioning is indicated by higher scores on the Functional Scale and the Global Health Scale. Whereas, higher scores on the Symptom Scale and on individual items indicate a greater number of symptoms or issues.<sup>14</sup>

### Functional Scale

All subscales of functional scales in the QLQ-C30, other than social functioning had significantly higher mean values in BC patients.<sup>15</sup> The majority of the study participants had poor emotional and social functioning<sup>16</sup>. The most difficult situations occurred at work and during leisure hours. Social functioning impairments were found to be more severe among functional scales. The highest function was found for role function. The social, cognitive, and physical functioning subscales yielded the best functional results. Physical function and role functioning were correlated with the highest QOL<sup>17</sup>. It was discovered that physical functioning and fatigue were the most affected by the burden, limitations, or need for assistance<sup>18</sup>.

### Symptom Scale

On the scale of symptoms, financial difficulties had afflicted 79.2 percent of participants.<sup>19</sup> Pain domain had higher scores. Fatigue was reported highest.<sup>20</sup> On the symptom scale, financial impact was the most distressing symptom. The symptoms of tiredness, difficulty sleeping, pain, and shortness of breath were accompanied by significantly elevated levels of stress.<sup>21</sup> The most alarming symptoms were fatigue and insomnia, followed by loss of appetite and pain. More severe and frequently reported impairments were observed on pain, insomnia, fatigue, financial difficulties, loss of appetite.<sup>3,10,22–24</sup>

In terms of functional and symptoms scale, no statistically significant difference was observed ( $p$  values  $> 0.050$ ).<sup>25</sup> The EORTC QLQ-C30's functional scale mean was high across most of the domains, particularly in terms of social functioning and cognitive functioning; whereas other items on symptom scales were moderate to low while global health status was high. The difference between scoring values in the function and symptom scales, except for the score fatigue, was significantly low.<sup>26</sup>

### The QOL-BR23

There are 23 questions in the QLQ-BR23 module divided into 2 scales, designed specifically for BC survivors. Each question uses a Likert scale, with the lowest value of 1 and higher value of 4. One of the two scales in this module is the Functional Scale, which has four questions about body image, two about sexual function, one about sexual pleasure, and one about future prospect. The second scale is Symptom Scale. It has seven items about systemic therapy, four about BC symptoms, three about arm symptoms, and one about hair loss.<sup>27</sup>

### Functional Scale

All subscales of functional scales of QLQ- BR23 were significantly higher in the patients with BC.<sup>15</sup> Amongst the functional scale, sexual functioning was most affected. Significant differences were found in the physical, role and emotional functioning. Sexual function, sexual enjoyment, and future perspective were less affected.<sup>28</sup> QOL was better for body image and future perspective. Future perspective and body image had the most severe impairments among functional scales. Sexual activity and sexual pleasure were found to have the highest function. The highest QOL was for body image. In terms of body image, sexual functioning, and sexual pleasure, there were significant differences.<sup>24</sup> Mastectomy patients were dissatisfied with their body images and thus body image component was affected. The future perspective and sexual intercourse satisfaction were negatively affected.<sup>29,30</sup>

### BR-23 Symptom Scale

The most unbearable symptom was breast symptom.<sup>19</sup> The item “upset by hair” was highly reported as severe impairment.<sup>31,32</sup> In BR-23 symptom scale, patients experienced more side effects of systemic therapy.<sup>20</sup> There were significant differences in sleep disturbance, arm symptoms, and lymphedema.<sup>16</sup> Fatigue, insomnia, arm symptoms, and upset by hair loss found to be significant.<sup>33</sup> The symptoms of arm pain and hair loss were the most frequently reported ones.<sup>22</sup> Almost 69% of all BC patients reported experiencing feelings of depression, irritability, tension, or anxiety.<sup>10</sup> Changes in depression status influenced differences in QOL.<sup>23</sup>

In the patient sample, all symptom scale items had higher mean scores, while the functional scale had a lower mean score (worse QOL).<sup>34</sup> The study showed that QOL was getting worse, with increase in symptom scale while decrease functional scales.<sup>35</sup> In terms of functional and symptoms scales, no statistically significant difference was observed ( $p$  values  $> 0.050$ ).<sup>25</sup>

## 5. DISCUSSION

The aim of this study was to learn about the most valid and reliable tool to assess the QOL among patients with BC. In this study, the authors collected and reviewed 39 articles based on the eligibility criteria. This review is in line with several studies conducted to validate the reliability of the European Organization for Research and Treatment for Cancer Quality of Life Questionnaires, QLQ-C30 & QLQ-BR23.

The incidence rate of BC as per the Indian Registry for Rural, Urban, Metro and North-eastern regions from 2008-2011 indicated for each city was taken from studies conducted to assess BC patients' QOL wherein EORTC QLQ-C30 and QLQ-BR23 questionnaires were used and it was reported as a significant tool.<sup>36</sup> A study provided evidence that depressive

symptoms in BC patients detrimentally reduced various aspects of QOL and also validated the reliability of EORTC QLQ-C30 and QLQ-BR23 questionnaires. The association of functional and symptoms scale of EORTC QLQ-C30 and QLQ-BR23 was demonstrated by a study and proved that these questionnaires are widely used tool among the BC population.<sup>15</sup> Many aspects of QOL were maximally affected in a study where BC patients were undergoing chemotherapy and were effectively demonstrated by these questionnaires.<sup>31</sup> Except for the sexual functioning scores of hormonally treated BC patients for whom these two questionnaires were used, the parameters of QOL were found to be better.<sup>20</sup> In a study the impact of BC surgery and its treatment on HRQOL demonstrated an average performance on most of the domains of these questionnaires except for sexual functioning, enjoyment, body image which showed poor functioning and overall reduced quality of life.<sup>37</sup> In another study, the impact of BC treatment on quality of life in BC survivors concluded that the highest score was observed with patients undergoing chemotherapy while the lowest was observed with patients undergoing hormonal therapy.<sup>25</sup> (Figure 4). A German study performed to assess the HRQOL in metastatic and adjuvant BC patients concluded that HRQOL of patients was significantly reduced in all areas, declaring the questionnaires to be an effective tool.<sup>21</sup>

The length of the treatment and QOL in BC were inversely proportional which was established by Damodar *et al* who used both these questionnaires to evaluate the QOL.<sup>38</sup> Another study demonstrated the strength of the relationship between clinical socio-demographic factors and BC patients' QOL using the C30 and BR23 questionnaires and concluded that psychological and financial support may enhance QoL.<sup>39</sup> The study conducted in Saudi Arabia to assess QOL in BC survivors demonstrated that functional scale domains of EORTC QLQ-C30 had high scores, whereas symptom scales had moderate to low scores whereas there were no discernible differences noted in domains of EORTC OLQ-BR23.<sup>35</sup>

Using both of these questionnaires, a study of the prognostic value of post-diagnosis HRQOL for overall survival in BC survivors found significant associations between functional scales and symptoms scales and overall survival.<sup>32</sup> A Chinese study that used both EORTC questionnaires found that people with higher function scores were more active and had a better outlook on life.<sup>40</sup> A Moroccan study conducted by Fakir *et al.* used these questionnaires to assess QOL in BC patients and concluded that the general HRQOL of the Moroccan population is lower than that of other comparable nations.<sup>10</sup> All EORTC QLQ-C30 subscales, with the exception of emotional function and future perspective, showed negative changes in QOL and anxiety in BC patients before and after treatment.<sup>34</sup> Four domains of the C30 questionnaire had significant correlations with illness acceptance and QOL in BC patients, while three domains of the BR23 questionnaire had positive correlations. The acceptance of the illness is directly proportional to QOL was proved by Jankowska *et al.*<sup>24</sup> When BC patients' QOL after a mastectomy was measured using C30 and BR23, it was found that they had a negative outlook on their health in the future and that their sexual functioning and enjoyment were profoundly impacted.<sup>29</sup> A study concluded association between diabetes and QOL among BC survivors with higher scores in symptom domain of C30 questionnaire.<sup>30</sup> The study's findings, which were used to determine clinical significance thresholds for four key domains of the EORTC QLQ-C30, revealed that the QLQ-C30 scales had high diagnostic accuracy in determining the reporting burden, limitations, and/or need for assistance of BC patients in relation to the four key domains of the C30—PF, EF, PA, and FA.<sup>18</sup> Recent studies have developed new tools like the BC utility instrument, BREAST-Q questionnaire which have good reliability and can be considered for clinical use.<sup>41,42</sup> Lymph-ICF questionnaire have proven reliable to measure BC surgery related lymphedema in upper limb.<sup>43</sup> According to the findings of a study that looked at the normative data for the EORTC QLQ-C30 HRQOL in European and North American countries, these new norm data make it possible to make valid comparisons between countries and within countries, and the QLQ C30 can be used to compare self-reported health-related QOL of cancer patients as well as in projects that span across multiple countries.<sup>44</sup> It is also established that the use of e-PRO tool of C30 questionnaire (digital based) was equally valid to paper-based C30 questionnaire. validity Hence, it makes this questionnaire to be easily accessible through digital means.<sup>26</sup> Table 4 gives a comprehensive comparison of all the scales used for assessing HRQOL in BC patients. The data shows that EORTC OLQ C-30 and BR-23 have good reliability and validity and assess all the major domains of HRQOL. FACT-B and FACT-G have also demonstrated good reliability, FACT-B being more specific to BC patients. Breast-Q questionnaire and breast utility instruments are comparatively newer tools having good reliability and validity but haven't been much used clinically. The HRQOL of BC patients can be positively assessed using the EORTC QLQ-C30 and QLQ-BR23 questionnaires.<sup>32</sup>

## 6. CONCLUSION

EORTC formulated the QLQ-C30 which helps to evaluate the QOL in cancer patients, whereas BR-23 is a BC specific questionnaire. As an outcome measurement, they provide metric QOL score in a meaningful way which can be used to make changes in interventions to improve the QOL. After reviewing 38 articles, it was established that each of these studies used either C30 or BR23 or both, to analyse the different domains of QOL in BC patients validating its efficacy. Therefore, it can be said that the EORTC questionnaires are the most valid and reliable tools in assessing the QOL in BC patients. It can be used in everyday clinical practice to identify patients who have clinically important problems that need more investigation and possible intervention by health care professionals.

## Conflicts of Interest

The authors declare that there are no conflicts of interest.

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