



Health-Related Quality of Life in Breast Cancer Patients during Chemotherapy: A Cross-Sectional Study Using the EORTC QLQ-C30 and BR45

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ABSTRACT

Objective: To assess health-related quality of life (HRQoL) using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Breast Cancer (EORTC QLQ-BR45) in conjunction with the Core questionnaire (EORTC QLQ-C30) in breast cancer patients receiving chemotherapy.

Materials and Methods: This prospective, cross-sectional study was conducted in the oncology department of a tertiary care hospital for six months. Patients aged ≥ 18 years, diagnosed with breast cancer, and who had received at least three chemotherapy cycles were included in the study. The EORTC (QLQ-BR45 and QLQ-C30) questionnaires were used to assess HRQoL at chemotherapy cycle 3 (C3) and at C6 and C9. Data were analyzed using the Mann-Whitney U and Friedman tests for significance ($p < 0.05$).

Results: The study showed improved global health status (C3:37.29%, C6:42.37%, C9:50%), high cognitive functioning (C3:89.83%, C6:91.53%, C9:96.55%), but decreasing emotional functioning (C3:66.10%, C6:49.15%, C9:36.21%). Symptom burden peaked in the sixth cycle but diminished over time with a trend towards fatigue (C3:64.41%, C6:67.80%, C9:37.93%), dyspnea (C3:54.24%, C6:55.93%, C9:32.76%), and pain (C3:42.37%, C6:52.54%, C9:34.48%). The study indicated satisfaction with body image (C3:61.02%, C6:67.80%, C9:67.24%) but decreased sexual functioning (C3:40.68%, C6:44.07%, C9:46.55%). Distress related to hair loss ($p = 0.0001$) increased over time.

Conclusion: There was increased symptom burden at C6, underscoring the need for early interventions. We observed severe symptoms in elderly. However, lack of comorbidities and metastasis improved the emotional wellbeing in patients. These findings accentuate the importance of personalized and holistic care approaches in oncology.

Keywords: Breast cancer; EORTC QLQ-BR45; EORTC QLQ-C30; health-related quality of life; PROM

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Key Points

- Younger patients and those who had surgery reported better functional outcomes, whereas older patients reported more severe symptoms, highlighting the need for age-specific treatment measures.
- The absence of comorbidities and metastasis was associated with improved emotional functioning, but there were challenges, such as increased insomnia.
- Symptom burden peaked during the sixth cycle of chemotherapy before progressively reducing, underscoring the need for early interventions to manage symptoms effectively.

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Introduction

Breast cancer is the most prevalent cancer worldwide, surpassing lung cancer by 11.7% in 2020 (1). It has among the highest per-patient expenditures in the health-care system and is diagnosed in one out of every eight women during their lifetime (2). In practically all constituent nations, it is one of the top three causes of early mortality (30–69 years) (3). According to a population-based study from the United States Cancer Statistics database, from 2010 through 2014, over 2.64 million cases and 1.7 million deaths from breast cancer will occur worldwide by 2030 (4, 5).

India has witnessed an estimated incidence of 13.5% of breast cancer cases and a 10.6% death rate, resulting in a cumulative risk of 2.81%, according to Globocan data 2020 (1). The Indian Ministry of Health and Family Welfare recorded 14,726/1,42,283 new cases in 2016, 15,522/1,50,842 in 2017, and 16,358/1,59,924 in Maharashtra in 2018. This demonstrates a clear increase in breast cancer cases in recent times (6). However, more advanced screening methods have made it possible to diagnose breast cancer sooner, and as new treatment choices have emerged, breast cancer survival has increased (7). Patients with breast cancer now have much-improved prognoses and outcomes, with a 10-year survival rate of approximately 78% (8). Depending on the site of metastasis, new therapeutic modalities have led to increased survival of patients with metastatic breast cancer. Approximately 90% of women who have breast cancer live for at least five years following their diagnosis (7). As a result of this advance, more breast cancer patients experience the short- and long-term effects of their disease and treatment, which has shifted the focus of care from immediate treatment outcomes to long-term health-related quality of life (HRQoL) (8).

HRQoL has emerged as a primary clinical outcome in cancer research over the past few decades. It encompasses physical, psychological, and social functioning and disease- and treatment-related symptoms (9, 10). QoL has also been acknowledged as a major outcome in clinical trials, potentially enhancing patient satisfaction and treatment effects (11, 12). Measuring QoL in cancer patients is important for predicting treatment responses, estimating survival times, and identifying common issues. Although QoL generally improves over time after breast cancer diagnosis, survivors often report worse QoL than healthy women and experience symptoms, such as sleep disturbance, cognitive impairment, fatigue, and various physiological reactions, including pain, nausea, vomiting, hair loss, and skin changes (13).

With improved survival rates, understanding the evolving needs of breast cancer patients has become more important. Although many studies have evaluated patients QoL, few have comprehensively examined patients from diagnosis to >10 years post-treatment, considering factors such as age, cancer stage, and treatment history (7). Moreover, there is little literature on QoL during active therapy, except for studies on the positive impact of breast conservation surgery on body image.

The aim of this study was to evaluate the HRQoL of breast cancer patients undergoing chemotherapy using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Breast Cancer (EORTC QLQ-C30), a general cancer-specific questionnaire that offers a comprehensive assessment of key QoL domains, and the EORTC QLQ-BR45, a breast cancer-specific module designed to examine disease and treatment-related factors. It was hoped that this investigation would facilitate an in-depth exploration of QoL

determinants and identifying critical areas for targeted intervention in breast cancer patients undergoing chemotherapy.

Materials and Methods

This prospective, cross-sectional study was conducted at the oncology department of a tertiary care hospital and was approved by the Institutional Ethics Committee of Bharati Hospital & Medical College, Pune (approval number: BVDUMC/IEC/23, date: 07.11.2023). The study was conducted over a period of six months from November 2023 to May 2024. Informed consent was obtained from all individual participants included in the study.

Inclusion Criteria

Patients aged 18 years and above, diagnosed with breast cancer and receiving chemotherapy, regardless of the stage of diagnosis, and who completed at least three cycles of chemotherapy were eligible for inclusion. Informed consent was obtained from all individual participants in the study.

Exclusion Criteria

Patients who had undergone surgical intervention without subsequent administration of chemotherapy and those who refused to provide consent to participate in the study were excluded.

Study tool

HRQoL was assessed using the EORTC QLQ-C30 version 3 and QLQ-BR45 Breast Phase IV module (14).

The EORTC QLQ-C30 consists of 30 questions that evaluate QoL based on physical, psychological, and social status. The three main components are: functional scales, physical, role, emotional, cognitive, and social functioning; symptom scales, fatigue, pain, nausea and vomiting, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial issues; and Global Health Status, which is an overall assessment of the patient's health and quality of life, offering a holistic view of well-being.

The EORTC QLQ-BR45 consists of 45 questions specifically designed for patients with breast cancer and evaluates both symptomatology and functional aspects. The functional scales included body image, breast satisfaction, sexual function, sexual enjoyment, and future perspectives. Symptom scales include systemic therapy side effects, hair loss concerns, arm symptoms, breast symptoms, endocrine therapy-related symptoms, skin mucositis symptoms, and endocrine sexual symptoms.

The EORTC QLQ-C30 and EORTC QLQ-BR45 scoring manuals were used to calculate the scores, and the range of responses was from 1 (not at all) to 4 (very much). The patient's health state and overall quality of life were the two questions used to assess the patient's global health status, with ratings ranging from one (very poor) to seven (excellent).

Both questionnaires were completed by all participants after the third chemotherapy cycle (C3) and after the subsequent sixth and ninth cycles (C6 and C9, respectively).

Statistical Analysis

All data were collected using Microsoft Office Excel 2019 for preliminary analysis. Continuous variables are represented as mean and standard deviation, and categorical variables are expressed as

frequencies and percentages. Statistical analyses were performed using SPSS, version 20 (IBM Inc., Armonk, NY, USA). The Mann-Whitney U test was used to compare the distribution of questionnaire scores between the patient groups, with significance set at $p < 0.05$. The Friedman test was used to detect repeated measurement differences between the different cycles (C3 vs. C6 vs. C9).

Results

This was a prospective, cross-sectional study that assessed HRQoL among female patients with breast cancer undergoing chemotherapy. Of the 206 patients with cancer admitted to the oncology ward during the study period, 64 patients with breast cancer received chemotherapy. From this group, 58 patients met the study criteria, participated in the study, and completed both questionnaires at three consecutive follow-up points, C3, C6 and C9.

The mean age of participants was 54.6 ± 11.2 years, with more than a third (34.4%) being over 60 years old. Most of the participants had completed primary school (55.5%), were professionally inactive (91.3%), lived in urban areas (62%), and were married (86.2%). A small fraction of the patients were tobacco chewers (13.7%), while only one patient (1.7%) reported alcohol consumption. A significant percentage of patients experienced loss of appetite (75.8%) and changes in food taste (70.6%). Body mass index analysis revealed that 53.4% of patients were within the normal weight range, 3.4% were underweight, and 13.7% were obese.

All patients received chemotherapy (100%), with 56.8% undergoing surgery, and one patient (1.7%) received radiotherapy. Postmenopausal status was prevalent in 89.6% of patients, while 10.3% were premenopausal. Comorbidities were reported by 36.2% of patients, and the majority (81%) did not show any signs of metastasis. The sociodemographic characteristics of patients are presented in Table 1.

EORTC QLQ-C30 and BR45 Scores at the Third, Sixth, and Ninth Cycles of Chemotherapy

In the analysis of the QLQ-C30 questionnaire, reported global health status improved throughout treatment, with scores increasing from 54.17 in C3 to 56.75 in C6, and 60.09 in C9. Significant improvements were noted across multiple functional domains following the third cycle of chemotherapy. Specifically, physical ($p = 0.026$), emotional ($p = 0.002$), social ($p = 0.002$), and cognitive functioning ($p = 0.006$) scores showed significant improvement in C6 and C9. Although reported role functioning showed a slight decline, this was not significant.

Symptom scales revealed statistically and clinically significant changes. There was an increasing trend in reported fatigue ($p = 0.028$) and dyspnea ($p = 0.012$) as treatment progressed. Conversely, several other symptoms were reported to improve after C3. Significant improvements were noted in scores for nausea and vomiting ($p < 0.001$), pain ($p = 0.008$), appetite loss ($p < 0.001$), constipation ($p < 0.001$), and diarrhea ($p = 0.001$), which collectively contributed to a lower overall symptom burden for patients as they progressed through their chemotherapy regimen.

Several statistically significant changes were also observed in the QLQ-BR45 scores over the three time points. Patients reported a modest reduction in future worries ($p = 0.043$), indicating a slightly more positive outlook as the treatment advanced. However, distress related to hair loss emerged as a prominent concern with a highly significant

increase ($p < 0.001$). In addition, significant improvements in reported arm symptoms ($p = 0.008$), breast symptoms ($p = 0.001$), endocrine therapy symptoms ($p = 0.001$), and skin mucositis symptoms ($p < 0.001$) were observed, all of which demonstrated marked reductions in the subsequent cycles when compared to C3 responses (Figure 1 and Table 2).

Table 1. Socio-demographics characteristics of breast cancer patients (n = 58) undergoing therapy at the third chemotherapy cycle which was equivalent to this study baseline

Characteristics	Variables	Number (%)
Age (in years)	18–40	5 (8.6)
	41–50	19 (32.7)
	51–60	14 (24.1)
	>60	20 (34.4)
	Mean ± standard deviation	54.6±11.2
Education	Illiterate	4 (6.8)
	Primary school	32 (55.1)
	Secondary school	17 (29.3)
	Above secondary school	5 (8.6)
Occupational status	Professionally inactive	53 (91.3)
	Professionally active	5 (8.6)
Residence	Urban	36 (62)
	Rural	22 (37.9)
Marital status	Married	50 (86.2)
	Widowed	8 (13.7)
	Social behaviors	Tobacco chewer
Alcohol consumer		1 (1.7)
Food habits		Loss of appetite
	Normal appetite	14 (24.1)
	Change in taste	41 (70.6)
	Underweight (<18.5)	2 (3.4)
Body mass index (in kg/m²)	Normal weight (18.5–24.9)	31 (53.4)
	Overweight (25–29.9)	17 (29.3)
	Obese (30–39.9)	8 (13.7)
Treatment	Chemotherapy	58 (100)
	Surgery	33 (56.8)
	Radiotherapy	1 (1.7)
Comorbidity	Yes	21 (36.2)
	No	37 (63.7)
Menopausal status	Postmenopausal	52 (89.6)
	Premenopausal	6 (10.3)
Metastasis	No	47 (81.0)
	Yes	11 (18.9)

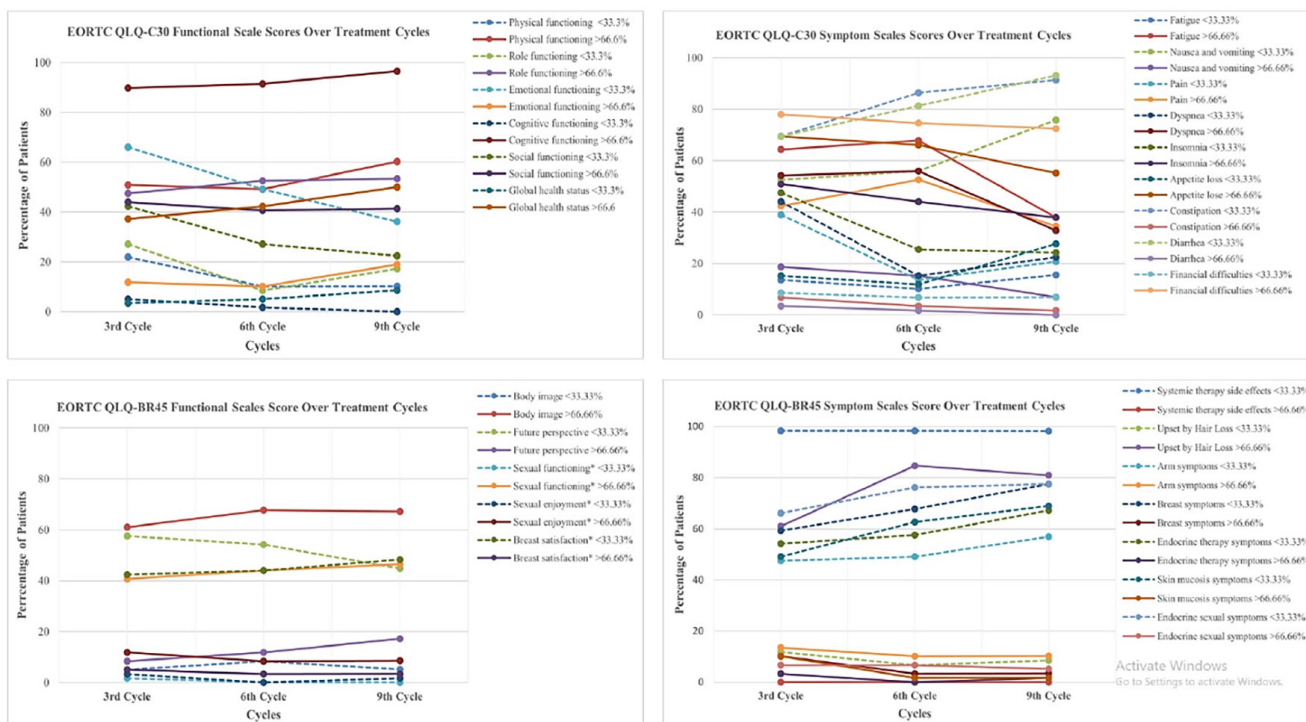


Figure 1. The EORTC QLQ-C30 and EORTC QLQ-BR45 scores (cycles three, six, and nine)

A higher score on functional scales indicates better functioning, while a higher score on symptom scales indicates worse functioning. Scoring <33.33% suggests a significant deterioration in QoL, while a score >66.66% indicates an improved QoL. Scoring <33.33% suggested a lower symptom burden, and scoring >66.66% indicated a significant symptom burden. Sexual enjoyment: applicable only to sexually active patients in the last four weeks before responding to the questionnaire. Upset by hair loss: applicable only to patients who have observed hair loss in the last week of responding to the questionnaire. Breast satisfaction: applicable only to patients who underwent surgery. *Reverse scoring items.

Analysis of Demographic Factors and Associations With EORTC QLQ-C30 Scores

Patients aged <50 years and those who had undergone surgery reported better physical functioning scores ($p = 0.004$ and $p = 0.044$, respectively). Cognitive functioning scores were also higher in patients aged <50 years ($p = 0.015$). However, this group of patients reported an increasing concern with fatigue ($p = 0.007$), pain ($p = 0.010$), and dyspnea ($p = 0.007$). Patients with no comorbidities and those with non-metastatic disease reported improvements in emotional functioning ($p = 0.050$ and $p = 0.007$, respectively). Nonetheless, patients with comorbidities reported a significant increase in insomnia ($p = 0.007$) and financial difficulties ($p = 0.040$). The absence of metastasis was also associated with an overall improvement in the global health status ($p = 0.019$). Pain was a significant symptom burden for postmenopausal women ($p = 0.049$). The analysis of the variables of the EORTC QLQ-C30 questionnaire is presented in Tables 3 and Table 4.

Analysis of Demographic Factors and Associations With EORTC QLQ-BR45 Scores

Patients with non-metastatic disease reported statistically significant changes in body image ($p = 0.004$) and future perspective ($p = 0.006$), whereas those aged ≥ 50 years suffered from more arm symptoms ($p = 0.004$) and endocrine therapy symptoms ($p = 0.0001$). Endocrine sexual symptoms were reported to be mildly persistent in patients who did not undergo surgery ($p = 0.027$) and those who did not have any comorbidities ($p = 0.034$). The analysis of the variables of the EORTC QLQ-BR45 is presented in Tables 5 and Table 6.

Discussion and Conclusion

The global health status of patients during chemotherapy improved significantly over the three cycles, indicating an improved quality of life as the therapy progressed. During each cycle, the functional scale scores showed positive outcomes, where the majority of patients recorded scores higher than 66.66%, with reported cognitive functioning achieving the highest scores, indicating that most patients demonstrated a sound mental capacity. While emotional functioning stayed below 33.33%. This could be due to physical side effects, psychological distress, and impact on daily life (15). A study by Kshirsagar and Wani (16) and Jassim and Whitford (17) also reported similar outcomes and found a significant reduction in emotional function. However, their studies did not clarify the cycle in which the data were collected, and it remains unclear whether there was a significant increase or decrease in emotional functioning throughout the progression of therapy.

Symptom scales indicated a negative impact on QoL, with an increased frequency of fatigue, followed by dyspnea and pain until the sixth cycle. Perceived financial issues recorded the highest scores (C3:77.97%, C6:74.58%, and C9:72.41%), while perception of problems with constipation and diarrhea received the lowest scores. Ionescu et al. (18) published similar results for both functional and symptom scales, with higher scores for cognitive functioning. However, insomnia (28.99%) was the most distressing symptom reported in their study, followed by fatigue (3.83%) and pain (12.85%).

Table 2. Mean scores of the EORTC QLQ-C30 and BR45 at the third, sixth, and ninth chemotherapy cycles

Items	Mean (SD) 3 rd Cycle	Mean (SD) 6 th Cycle	Mean (SD) 9 th Cycle	<i>p</i>
Global health status/QoL				
Global health status/QoL	54.17 (15.39)	56.75 (15.17)	60.09 (19.40)	0.070
Functional scales/items				
Physical functioning	59.08 (26.88)	62.87 (24.31)	65.38 (24.25)	0.026*
Role functioning	58.33 (27.26)	58.33 (28.83)	57.02 (31.33)	0.983
Emotional functioning	31.18 (20.68)	32.04 (22.01)	39.62 (24.31)	0.002*
Cognitive functioning	85.92 (19.70)	89.37 (17.30)	92.40 (12.33)	0.002*
Social functioning	47.99 (35.88)	50.29 (34.41)	53.80 (33.04)	0.006*
Symptom scales/items				
Fatigue	64.56 (21.37)	62.26 (22.22)	54.58 (29.49)	0.028*
Nausea and vomiting	31.61 (28.56)	26.72 (25.35)	15.50 (20.62)	0.0001*
Pain	54.02 (26.91)	54.02 (25.04)	46.20 (28.35)	0.008*
Dyspnea	54.02 (31.11)	48.85 (27.37)	39.18 (28.95)	0.012*
Insomnia	48.28 (35.96)	42.53 (31.71)	39.18 (28.26)	0.076
Appetite loss	66.67 (36.94)	61.49 (32.92)	44.44 (31.71)	0.0001*
Constipation	12.64 (22.36)	5.17 (15.04)	2.92 (11.41)	0.0001*
Diarrhea	10.92 (18.08)	6.32 (14.59)	1.75 (7.51)	0.001*
Financial difficulties	64.94 (28.22)	66.09 (28.95)	65.50 (29.52)	0.905
EORTC QLQ-BR45				
Functional scales/items				
Body image	72.99 (23.89)	71.70 (25.26)	73.68 (24.64)	0.482
Future perspective	16.67 (21.85)	18.97 (23.46)	25.15 (27.66)	0.043*
Sexual functioning	82.26 (29.17)	85.48 (24.62)	86.46 (23.36)	-
Sexual enjoyment	50.00 (28.33)	56.67 (27.44)	53.33 (32.20)	-
Breast satisfaction	14.22 (27.26)	11.76 (22.67)	10.29 (22.10)	-
Symptom scales/items				
Systemic therapy side effects	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	-
Upset by hair loss	63.79 (36.02)	78.16 (29.65)	74.85 (31.67)	0.0001*
Arm symptoms	32.76 (25.10)	30.46 (24.85)	25.34 (21.49)	0.008*
Breast symptoms	26.58 (21.71)	21.55 (19.37)	18.42 (20.09)	0.001*
Endocrine therapy symptoms	31.21 (14.89)	28.45 (13.94)	25.26 (17.09)	0.001*
Skin mucosis symptoms	30.84 (22.10)	25.96 (17.27)	21.64 (17.31)	0.0001*
Endocrine sexual symptoms	16.38 (24.63)	11.78 (22.35)	9.94 (19.38)	-

*Statistically significant; higher scores on functional scales/items indicate better functioning; higher scores on symptom scales/items indicate more symptoms; SD: Standard deviation

The patients were notably content with their body image. However, sexual dysfunction posed a serious challenge. According to the score values, most patients either declined to answer this section or had no interest in engaging in any sexual activity during the four weeks before completing the questionnaire, whereas patients who were sexually active experienced sexually related issues. This concurs with the observations of Kidayi et al. (3), who highlighted the cultural context of Tanzania, where people are hesitant or forbidden from freely discussing sexual matters. Therefore, there were relatively fewer responses to the sexuality questions, which influenced the

statistical evaluation. In India, such topics are often considered taboo and rarely discussed in the community and as a result, sexual dysfunction remains an unidentified and neglected condition in breast cancer patients who, in most cases, experience a decline in sexual desire induced by cancer and treatment (19, 20).

There was a significant improvement in the future perspective of patients, indicating hope for disease therapy success. The symptom burden was comparatively low for breast, endocrine therapy, and skin mucosis symptoms and showed significant improvement throughout

therapy. However, chemotherapy-induced hair loss progressed throughout each cycle, leaving many patients in distress, which aligns with findings of a study from Brazil (21).

Regarding the functional scales in the QLQ-C30, this study showed that patients aged <50 years had a positive impact on physical and cognitive functioning compared with those aged ≥50 years. In the context of symptom scales, fatigue and shortness of breath were elevated in patients aged ≥50 years. This group of patients, as well as those who were postmenopausal, had body pain. These findings are consistent with the study by Imran et al. (22) highlighting the impact of age and menopausal status on functional and symptom scales.

Based on the results of the QLQ-BR45, the older population (≥50 years) experienced endocrine therapy symptoms, including hot flashes, excess sweating, joint pain, fatigue, and mood changes. Arm symptoms (discomfort, swelling, stiffness, numbness, tingling sensation, or sensitivity) were also evident in this age group. This may be because older patients who are postmenopausal at the time

of diagnosis potentially experience menopausal symptoms, such as hot flashes and vaginal dryness, but the addition of chemotherapy-induced menopause may exacerbate these already existing symptoms and pose additional issues, including deterioration of bone health, resulting in the prevalence of pain symptoms (23). Nisha et al. (24) prospectively suggested and confirmed a significant worsening of bone health associated with cytotoxic chemotherapy, as evidenced by 2% reduction in bone mineral density, which continued to worsen during follow-up, even after the completion of chemotherapy.

There was a notable transition from premenopausal to postmenopausal status in one patient, which presents evidence that patients below the age of 50 years, with a premenopausal status at cancer diagnosis are at risk of premature ovarian failure and compromised future fertility due to chemotherapy-induced ovarian suppression. Premenopausal women may experience higher rates of chemotherapy-induced amenorrhea and ovarian toxicity, which could increase the risk of infertility, early menopause, and hormonal imbalance post-treatment (25). Ursini et al. (11) expressed QoL in terms of implications associated with age, where

Table 3. Analysis of variables in the functional scales and global health status in the EORTC QLQ-C30

Variables	PF mean (SD)	RF mean (SD)	CF mean (SD)	EF mean (SD)	SF mean (SD)	Global Health Status mean (SD)
Age						
≥50 years (n = 36)	56.60 (23.49)	54.78 (28.37)	86.88 (17.80)	34.11 (22.89)	48.15 (33.28)	56.56 (16.23)
<50 years (n = 21)	73.86 (23.35)	64.55 (28.63)	94.18 (13.10)	35.45 (21.84)	56.35 (35.47)	58.73 (17.09)
p-value	0.004*	0.185	0.015*	0.741	0.273	0.533
Menopausal status [▲]						
Pre-menopause (n = 6)	75.93 (49.46)	70.37 (58.18)	98.15 (34.24)	31.02 (44.90)	74.07 (65.51)	63.89 (32.43)
Post-menopause (n = 51)	61.44 (24.21)	56.97 (21.05)	88.56 (5.39)	35.02 (23.71)	48.48 (36.26)	56.59 (19.17)
p-value	0.243	0.415	0.208	0.284	0.205	0.267
Comorbidities						
Yes (n = 20)	62.89 (23.69)	51.67 (30.95)	90.00 (17.95)	28.89 (23.19)	51.67 (30.49)	58.19 (19.01)
No (n = 37)	63.00 (25.52)	62.01 (26.98)	89.34 (15.86)	37.48 (21.52)	50.90 (36.23)	56.91 (15.11)
p-value	0.861	0.225	0.726	0.050*	0.873	0.580
Surgery						
Yes (n = 33)	67.88 (24.02)	56.57 (30.01)	90.74 (14.53)	36.87 (23.72)	48.32 (32.95)	58.08 (15.86)
No (n = 24)	56.20 (24.46)	60.88 (27.00)	87.96 (19.02)	31.48 (20.33)	55.09 (35.78)	56.37 (17.50)
p-value	0.044*	0.686	0.685	0.365	0.471	0.626
Presence of metastasis [▼]						
Yes (n = 10)	63.33 (19.08)	47.78 (21.32)	89.44 (15.46)	21.67 (18.52)	44.44 (26.74)	50.00 (15.32)
No (n = 47)	62.88 (25.93)	60.64 (29.70)	89.60 (16.85)	37.35 (22.31)	52.60 (35.54)	58.92 (16.42)
p-value	0.919	0.066	0.472	0.007*	0.816	0.019*
Change in taste						
Change (n = 40)	61.03 (22.29)	55.56 (29.20)	90.31 (13.88)	31.48 (21.16)	50.14 (31.83)	56.13 (15.33)
No change (n = 17)	67.16 (29.36)	64.51 (27.10)	87.96 (21.33)	41.36 (23.84)	53.40 (39.17)	60.03 (18.77)
p-value	0.276	0.147	0.722	0.637	0.484	0.211

*Statistically significant; higher scores on functional scales/items indicate better functioning (PF, physical functioning; RF: Role functioning; EF: Emotional functioning; CF: Cognitive functioning; SF: Social functioning; SD: Standard deviation). [▲]: Observed transition from the premenopausal state to postmenopausal state in one patient in cycle six. [▼]: Observed non-metastatic state from the presence of metastasis in one patient in cycle nine

Table 4. Analysis of variables in symptom scales in the EORTC QLQ-C30

Variables	FA mean (SD)	NV mean (SD)	PA mean (SD)	DY mean (SD)	SL mean (SD)	AP mean (SD)	CO mean (SD)	DI mean (SD)	FI mean (SD)
Age									
≥50 years (n = 36)	65.74 (23.34)	22.84 (23.08)	57.10 (23.26)	54.32 (25.21)	46.30 (31.52)	57.41 (36.12)	7.72 (19.12)	4.94 (11.90)	64.81 (28.76)
<50 years (n = 21)	50.26 (23.77)	25.93 (28.52)	40.21 (28.50)	33.86 (31.39)	38.62 (33.44)	56.61 (33.14)	5.82 (14.09)	7.41 (16.33)	65.61 (28.69)
p-value	0.007*	0.739	0.010*	0.007*	0.240	0.632	0.936	0.416	0.890
Menopausal status[†]									
Pre-menopause (n = 6)	50.00 (48.81)	21.30 (49.49)	28.70 (51.69)	37.04 (57.97)	40.74 (66.70)	51.85 (70.60)	7.41 (36.05)	14.81 (23.54)	61.11 (54.68)
Post-menopause (n = 51)	61.22 (26.47)	24.29 (31.21)	53.49 (24.79)	47.93 (32.11)	43.79 (26.95)	57.73 (30.73)	6.97 (14.26)	4.79 (23.49)	65.58 (34.77)
p-value	0.808	0.203	0.049*	0.678	0.732	0.482	0.906	0.135	0.712
Comorbidities									
Yes (n = 20)	62.78 (24.96)	25.83 (25.20)	48.61 (24.98)	48.33 (27.05)	31.11 (31.81)	46.67 (34.83)	6.67 (14.78)	7.22 (15.15)	75.00 (25.77)
No (n = 37)	58.56 (24.39)	22.97 (25.23)	52.10 (27.35)	45.95 (30.50)	50.15 (30.77)	62.76 (33.86)	7.21 (18.75)	5.11 (12.87)	59.76 (28.82)
p-value	0.514	0.602	0.757	0.756	0.007*	0.054	0.392	0.597	0.040*
Surgery									
Yes (n = 33)	56.12 (25.86)	23.06 (23.77)	47.47 (27.60)	43.77 (32.52)	39.39 (33.46)	52.86 (36.89)	7.41 (18.78)	5.72 (13.50)	65.66 (29.53)
No (n = 24)	65.43 (21.79)	25.23 (27.12)	55.56 (24.39)	50.93 (23.72)	49.07 (30.11)	62.96 (31.43)	6.48 (15.46)	6.02 (14.07)	64.35 (27.59)
p-value	0.117	0.852	0.293	0.733	0.185	0.265	0.828	0.551	0.710
Presence of metastasis[‡]									
Yes (n = 10)	62.96 (23.77)	22.78 (22.52)	55.56 (27.80)	52.22 (27.24)	38.89 (32.85)	57.78 (33.83)	3.33 (10.17)	5.56 (15.37)	74.44 (29.92)
No (n = 47)	59.42 (24.81)	24.23 (25.78)	49.88 (26.24)	45.63 (29.66)	44.44 (32.29)	56.97 (35.31)	7.80 (18.53)	5.91 (13.38)	63.12 (28.09)
p-value	0.352	0.699	0.517	0.227	0.927	0.878	0.834	0.972	0.169
Change in taste									
Change (n = 40)	61.44 (23.42)	19.52 (21.47)	53.28 (24.20)	47.86 (26.76)	43.31 (29.77)	60.11 (32.82)	4.56 (11.50)	5.70 (14.04)	63.82 (28.89)
No change (n = 17)	57.00 (26.96)	33.64 (29.76)	45.68 (30.58)	44.44 (34.26)	43.83 (37.66)	50.62 (38.71)	12.35 (25.32)	6.17 (13.07)	67.90 (28.20)
p-value	0.917	0.133	0.848	0.868	0.419	0.595	0.180	0.668	0.505

*Statistically significant; Higher scores on symptom scales/items indicate more symptoms. (FA: Fatigue; NV: Nausea and vomiting; PA: Pain; DY: Dyspnea; SL: Insomnia; AP: Appetite loss; CO: Constipation; DI: Diarrhea; FI: Financial difficulties; SD: Standard deviation). †: Observed transition from premenopausal state to postmenopausal state in one patient in cycle six. ‡: Observed non-metastatic state from the presence of metastasis in one patient in cycle nine

Table 5. Analysis of variables in functional scales in the EORTC QLQ-BR45.

Variables	BI mean (SD)	FU mean (SD)	SX‡ mean (SD)#	SE‡ mean (SD)^	BS‡ mean (SD)¶
Age					
≥50 years (n = 36)	75.31 (23.71)	19.14 (24.20)	97.84 (7.96)	77.78 (17.21)	11.38 (18.65)
<50 years (n = 21)	69.97 (24.48)	22.75 (25.28)	67.08 (30.31)	47.22 (27.66)	13.96 (31.55)
p-value	0.475	0.452	-	-	-
Menopausal status[▲]					
Pre-menopause (n = 6)	73.69 (25.44)	20.92 (20.61)	89.45 (24.23)	53.70 (33.21)	12.41 (17.21)
Post-menopause (n = 51)	70.37 (23.96)	16.67 (25.04)	60.00 (23.14)	52.78 (25.92)	11.11 (24.56)
p-value	0.817	0.371	-	-	-
Comorbidities					
Yes (n = 20)	73.47 (22.58)	16.67 (25.67)	88.15 (25.78)	44.44 (23.57)	5.13 (12.18)
No (n = 37)	73.27 (24.93)	22.52 (23.85)	81.63 (25.29)	57.14 (30.08)	16.94 (28.46)
p-value	0.993	0.133	-	-	-
Surgery					
Yes (n = 33)	69.87 (23.20)	20.88 (24.55)	89.09 (25.50)	51.85 (33.79)	8.24 (16.23)
No (n = 24)	78.13 (24.56)	19.91 (24.81)	78.63 (24.76)	53.97 (26.82)	66.67 (43.03)
p-value	0.154	0.710	-	-	-
Presence of metastasis[▼]					
Yes (n = 10)	53.61 (19.14)	8.89 (17.72)	93.52 (15.48)	66.67 (0.00)	16.03 (36.23)
No (n = 47)	77.54 (22.71)	22.93 (25.24)	82.68 (27.14)	51.85 (29.72)	11.04 (20.51)
p-value	0.004*	0.006*	-	-	-
Change in taste					
Change (n = 40)	70.66 (23.07)	17.38 (22.57)	87.57 (23.94)	50.00 (30.78)	13.13 (23.48)
No change (n = 17)	79.17 (25.33)	27.16 (27.53)	79.03 (28.21)	58.33 (25.13)	10.78 (25.58)
p-value	0.201	0.551	-	-	-

*Statistically significant; higher scores on functional scales/items indicate better functioning (BI: Body Image; FU: Future Perspective; SX: Sexual Functioning; SE: Sexual Enjoyment; BS: Breast Satisfaction; SD: Standard deviation). ‡: Missing data due to refusal to answer the questions regarding SX, SE, and BS (#: n = 32; ^: n = 10; ¶: n = 34). ▲: Observed transition from premenopausal state to postmenopausal state in one patient in cycle 6. ▼: Observed non-metastatic state from the presence of metastasis in one patient in cycle 9

induction of early menopause and possible infertility increased the risk of adverse effects in younger women. This patient group is more likely to have a lower QoL and is more vulnerable to the emotional burden and psychological impact of breast cancer.

The present study showed that emotional functioning was significantly better in patients who did not have any comorbidities. Endocrine sexual symptoms and insomnia were also prevalent in this subgroup. However, the perception of worsened financial burden was significantly higher in comorbid patients, resulting in further deterioration of the symptom scales.

Patients who underwent surgery experienced good physical functioning, whereas those who did not undergo surgery showed an increase in endocrine sexual symptoms. Jassim et al. (17) suggested reasons for disrupted sexual function, such as low self-esteem, abrupt menopause, vaginal dryness, a partner's difficulties comprehending one's feelings, and body image issues.

Based on the findings of the EORTC QLQ-BR45, improved emotional function and an overall positive outcome in the global health status were recorded in non-metastatic patients compared to metastatic patients. Guo et al. (26) found that the prevalence of psychological burdens, such as depression, anxiety, and stress, were high in patients with metastatic breast cancer. Furthermore, the present study emphasized that future concerns about illness were relieved, and body image was less altered in patients who did not present with metastasis, when compared to the metastatic breast cancer group. There was a positive transition from metastatic to non-metastatic status in one patient.

In the present study, the QoL did not correlate with the chemotherapy agent given or the stage of cancer; hence, the results are based on the perceptions of patients who received a variety of chemotherapeutic regimens regardless of disease stage. Furthermore, the assessment of QoL before commencing or after completing therapy was not performed, as the two QoL instruments were applied at only three

Table 6. Analysis of variables in symptom scales in the EORTC QLQ-BR45

Variables	SYS mean (SD)	HU mean (SD)	ARM mean (SD)	BR mean (SD)	ET mean (SD)	SM mean (SD)	ES mean (SD)
Age							
≥50 years (n = 36)	0.00 (0.00)	71.91 (29.24)	36.01 (24.06)	24.00 (21.64)	32.84 (14.08)	28.70 (18.13)	12.58 (23.39)
<50 years (n = 21)	0.00 (0.00)	71.96 (38.89)	19.05 (19.80)	19.58 (18.58)	21.11 (14.93)	20.99 (20.07)	13.36 (20.66)
p-value	1.000	0.404	0.004*	0.501	0.0001*	0.056	0.677
Menopausal status*							
Pre-menopause (n = 6)	0.00 (0.00)	71.02 (30.55)	31.59 (20.10)	22.88 (19.44)	29.67 (10.55)	26.29 (23.18)	13.24 (16.97)
Post-menopause (n = 51)	0.00 (0.00)	79.63 (33.27)	14.20 (23.78)	18.06 (20.76)	18.70 (15.54)	22.22 (18.69)	9.72 (22.93)
p-value	1.000	0.442	0.094	0.807	0.070	0.543	0.441
Comorbidities							
Yes (n = 20)	0.00 (0.00)	75.00 (32.26)	30.56 (25.19)	19.31 (21.89)	29.94 (15.78)	21.57 (16.34)	6.94 (16.03)
No (n = 37)	0.00 (0.00)	70.27 (33.44)	29.33 (23.39)	24.02 (19.81)	27.75 (15.26)	28.18 (20.24)	16.07 (24.61)
p-value	1.000	0.366	0.987	0.254	0.519	0.157	0.034*
Surgery							
Yes (n = 33)	0.00 (0.00)	69.70 (34.04)	29.41 (24.35)	22.39 (22.51)	27.31 (14.90)	24.47 (19.16)	9.93 (22.61)
No (n = 24)	0.00 (0.00)	75.00 (31.52)	30.25 (23.61)	22.34 (17.85)	30.19 (16.10)	27.78 (19.15)	16.90 (21.53)
p-value	1.000	0.458	0.974	0.638	0.789	0.414	0.027*
Presence of metastasis*							
Yes (n = 10)	0.00 (0.00)	81.11 (29.45)	32.96 (19.91)	16.11 (20.31)	31.56 (17.21)	27.41 (21.71)	11.67 (21.60)
No (n = 47)	0.00 (0.00)	69.98 (33.17)	29.08 (24.76)	23.70 (20.68)	27.87 (15.20)	25.53 (18.79)	13.12 (22.87)
p-value	1.000	0.054	0.863	0.429	0.485	0.863	0.619
Change in taste							
Change (n = 40)	0.00 (0.00)	79.77 (25.13)	30.48 (21.79)	20.80 (18.65)	30.46 (14.95)	26.50 (19.44)	9.83 (19.56)
No change (n = 17)	0.00 (0.00)	54.94 (41.03)	28.19 (28.28)	25.77 (24.19)	24.32 (15.79)	24.49 (18.68)	19.44 (26.50)
p-value	1.000	0.062	0.462	0.211	0.295	0.965	0.153

*Statistically significant; higher score in symptom scale/items indicates more symptoms (SYS: Systemic therapy side effects; HU: Upset by hair loss; ARM: Arm symptoms; BR: Breast symptoms; ET: Endocrine therapy symptoms; SM: Skin mucosis symptoms; ES: Endocrine sexual symptoms; SD: Standard deviation). ▲: Observed transition from premenopausal state to postmenopausal state in one patient in cycle 6. ▼: Observed non-metastatic state from the presence of metastasis in one patient in cycle 9

specific points in time during chemotherapy. Thus, it is challenging to identify patterns of QoL over the long term or changes in their relationship with cancer-related symptoms. Further longitudinal studies and clinical trials should be conducted, leveraging large populations to track QoL outcomes over extended periods, including during and after chemotherapy, to better understand the trajectory of patient well-being.

Study Limitations

The limitations of this study include the small sample size, single-center design, and lack of baseline assessment before treatment, which may limit generalizability. Cultural factors may influence self-reported data, particularly for sensitive topics. Despite these limitations, this study provides valuable insights into the QoL of breast cancer patients during chemotherapy.

In conclusion, this study demonstrated that the quality of life of Indian patients with breast cancer during chemotherapy was influenced by a complex interplay of treatment-related factors, many of which are likely to affect patients from other populations, and patient demographics. A relatively stable global health status and good cognitive functioning were observed, with mild improvements in emotional functioning over time. Symptom burden peaked in the sixth cycle before gradually decreasing. Younger patients and those who underwent surgery showed better functional outcomes, although the latter experienced increased endocrine sexual symptoms. Older patients reported more severe symptoms than younger patients. The absence of comorbidities and metastasis was associated with improved emotional functioning, albeit with some trade-offs such as increased insomnia. These findings highlight the importance of personalized and holistic care in oncology. Potential areas for targeted interventions have been identified which may enhance patient well-being throughout the treatment journey. Furthermore, the pivotal role of clinical pharmacists in optimizing medication management, minimizing adverse effects, and providing patient education was evident.

Future research should focus on finding and assessing therapies targeted for specific patient subgroups to improve HRQoL outcomes in patients with breast cancer during chemotherapy. By integrating these insights into clinical practice, it may be possible to work towards more patient-centred and effective cancer care.

Ethics

Ethics Committee Approval: This prospective, cross-sectional study was conducted at the oncology department of a tertiary care hospital and was approved by the Institutional Ethics Committee of Bharati Hospital & Medical College, Pune (approval number: BVDUMC/IEC/23, date: 07.11.2023).

Informed Consent: Informed consent was obtained from all individual participants included in the study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: A.C.; Concept: A.R.; Design: A.H.A., A.R.; Data Collection or Processing: A.H.A., P.K., J.S., J.P.K., S.R.K.; Analysis or Interpretation: A.H.A., J.S., J.A.C., A.R.; Literature Search: A.H.A., P.K., J.S., J.P.K., S.R.K., A.R.; Writing: A.H.A., P.K., J.S., J.P.K., S.R.K., A.C., A.R.

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References

- Mehrotra R, Yadav K. Breast cancer in India: present scenario and the challenges ahead. *World J Clin Oncol.* 2022; 13: 209-218. (PMID: 35433294) [[Crossref](#)]
- Tsui TCO, Trudeau M, Mitsakakis N, Torres S, Bremner KE, Kim D, et al. Developing a breast utility instrument, a preference-based instrument to measure health-related quality of life in women with breast cancer: confirmatory factor analysis of the EORTC QLQ-C30 and BR45 to establish dimensions. *PLoS One.* 2022; 17: e0262635. (PMID: 35120148) [[Crossref](#)]
- Kidayi PL, Pakpour AH, Saboonchi F, Bray F, Manhica H, Mtuya CC, et al. Cross-cultural adaptation and psychometric properties of the Swahili version of the European Organization for Research and Treatment of Cancer (EORTC) QLQ-BR45 among breast cancer patients in Tanzania. *Healthcare (Basel).* 2023; 11: 2467. (PMID: 37761665) [[Crossref](#)]
- Scott LC, Mobley LR, Kuo T-M, Il'yasova D. Update on triple-negative breast cancer disparities for the United States: a population-based study from the United States Cancer Statistics database, 2010 through 2014. *Cancer.* 2019; 125: 3412-3417. (PMID: 31282032) [[Crossref](#)]
- Wang H, Yang Y, Zhang X, Shu Z, Tong F, Zhang Q, et al. Research on Mindfulness-based stress reduction in patients with breast cancer undergoing chemotherapy: an observational pilot study. *Altern Ther Health Med.* 2023; 29: 228-232. (PMID: 37023321) [[Crossref](#)]
- Ministry of Health and Family Welfare. Cervical and breast cancer cases in women [Internet]. Delhi: Press Information Bureau; 2020 Feb 11 [cited 2024 Nov 22]. [[Crossref](#)]
- Hamer J, McDonald R, Zhang L, Verma S, Leahey A, Ecclestone C, et al. Quality of life (QOL) and symptom burden (SB) in patients with breast cancer. *Support Care Cancer.* 2017; 25: 409-419. (PMID: 27696078) [[Crossref](#)]
- Bjelic-Radisic V, Cardoso F, Cameron D, Brain E, Kuljanic K, da Costa RA, et al. An international update of the EORTC questionnaire for assessing quality of life in breast cancer patients: EORTC QLQ-BR45. *Ann Oncol.* 2020; 31: 283-288. (PMID: 31959345) [[Crossref](#)]
- Ehab BH, Hussein RRS, Abdullah EA, Ahmed ZM, Elsherbiny RM. Cultural adaptation and validation of the EORTC QLQ-BR45 to assess health-related quality of life of breast cancer patients. *Eur Pharm J.* 2021; 68: 41-48. [[Crossref](#)]
- Getu MA, Wang P, Kantelhardt EJ, Seife E, Chen C, Addissie A. Translation and validation of the EORTC QLQ-BR45 among Ethiopian breast cancer patients. *Sci Rep.* 2022; 12: 605. (PMID: 35906247) [[Crossref](#)]
- Ursini LA, Nuzzo M, Rosa C, Di Guglielmo FC, Di Tommaso M, Trignani M, et al. Quality of life in early breast cancer patients: a prospective observational study using the FACT-B questionnaire. *In Vivo.* 2021; 35: 1821-1828. (PMID: 33910868) [[Crossref](#)]
- Pandey M, Thomas BC, Ramdas K, Eremenco S, Nair MK. Quality of life in breast cancer patients: validation of a FACT-B Malayalam version. *Qual Life Res.* 2002; 11: 87-90. (PMID: 12018741) [[Crossref](#)]
- Jang MK, Kim SH, Ko YH, Han J, Kim SY, Kim S. Comparing disease-specific and generic quality of life in Korean breast cancer survivors using the FACT-B and QLI: the importance of instrument selection. *Integr Cancer Ther.* 2022; 21: 15347354221085491. (PMID: 35289219) [[Crossref](#)]
- EORTC - Quality of Life [Internet]. Brussels: EORTC - Quality of Life; 2017 [cited 2024 Apr 29]. [[Crossref](#)]
- Cáceres MC, Nadal-Delgado M, López-Jurado C, Pérez-Civantos D, Guerrero-Martín J, Durán-Gómez N. Factors related to anxiety,

- depressive symptoms and quality of life in breast cancer. *Int J Environ Res Public Health*. 2022; 19: 3547. (PMID: 35329232) [\[Crossref\]](#)
16. Kshirsagar AS, Wani SK. Health-related quality of life in patients with breast cancer surgery and undergoing chemotherapy in Ahmednagar district. *J Cancer Res Ther*. 2021; 17: 1335-1338. [\[Crossref\]](#)
 17. Jassim GA, Whitford DL. Quality of life of Bahraini women with breast cancer: a cross sectional study. *BMC Cancer*. 2013; 13: 212. (PMID: 23622020) [\[Crossref\]](#)
 18. Ionescu Miron AI, Anghel AV, Antone-Iordache IL, Atasiei DI, Anghel CA, Barnonschi AA, et al. Assessing the impact of organ failure and metastases on quality of life in breast cancer patients: a prospective study based on utilizing EORTC QLQ-C30 and EORTC QLQ-BR45 questionnaires in Romania. *J Pers Med*. 2024; 14: 214. (PMID: 38392647) [\[Crossref\]](#)
 19. Daniel S, Venkateswaran C, Hutchinson A, Johnson MJ. 'I don't talk about my distress to others; I feel that I have to suffer my problems...'Voices of Indian women with breast cancer: a qualitative interview study. *Supportive Care in Cancer*. 2021; 29: 2591-2600. (PMID:32955655) [\[Crossref\]](#)
 20. Cernikova KA, Kracmarova LK, Pesoutova M, Tavel P. We will be different forever: a qualitative study of changes of body image in women with breast cancer. *BMC Public Health*. 2024; 24: 2517. (PMID: 39285297) [\[Crossref\]](#)
 21. Marcelo Castro e Silva I, Lúcia Penteadó Lancellotti C. Health-related quality of life in women with breast cancer undergoing chemotherapy in Brazil. *Int J Gen Med*. 2021; 10265-10270. (PMID: 34992441) [\[Crossref\]](#)
 22. Imran M, Al-Wassia R, Alkhayyat SS, Baig M, Al-Saati BA. Assessment of quality of life (QoL) in breast cancer patients by using EORTC QLQ-C30 and BR-23 questionnaires: a tertiary care center survey in the western region of Saudi Arabia. *PloS one*. 2019; 14: e0219093. (PMID: 31291302) [\[Crossref\]](#)
 23. Peacock K, Carlson K, Ketvertis KM, Doerr C. Menopause (Nursing). 2023 Dec 21. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. (PMID: 33760453) [\[Crossref\]](#)
 24. Nisha Y, Dubashi B, Bobby Z, Sahoo JP, Kayal S, Ananthakrishnan R, et al. Cytotoxic chemotherapy is associated with decreased bone mineral density in postmenopausal women with early and locally advanced breast cancer. *Arch Osteoporos*. 2023; 18: 41. (PMID: 36899284) [\[Crossref\]](#)
 25. Reynolds AC, McKenzie LJ. Cancer treatment-related ovarian dysfunction in women of childbearing potential: management and fertility preservation options. *J Clin Oncol*. 2023; 41: 2281-2292. (PMID: 36888938) [\[Crossref\]](#)
 26. Guo YQ, Ju QM, You M, Liu Y, Yusuf A, Soon LK. Depression, anxiety and stress among metastatic breast cancer patients on chemotherapy in China. *BMC Nurs*. 2023; 22: 33. (PMID: 36747213) [\[Crossref\]](#)