Review

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Health-Related Quality of Life in Women With Breast Cancer Undergoing Treatment With Hormonal Therapy – A Review Study

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ABSTRACT

This review aimed to analyze the significance and impact of health-related quality of life (QoL) in women with breast cancer undergoing treatment with hormonal therapy. This study developed a comprehensive, structured, systematic search strategy to identify literature related to health and QoL in breast cancer patients undergoing treatment with hormonal therapy. The search was conducted for published literature indexed in PubMed (Medline), Cancer Lit, CINAHL, Google Scholar, and Web of Science between 2010 and 2020. Patients associated with the study of QoL reported some difficulties in terms of depression, anxiety, chronic fatigue, sleep problems, pain, sexual dysfunction and sleep disorders. Endocrine-related symptoms did not fluctuate between interventions and remained unchanged in all groups. The evaluation of FACT-G scores (physical well-being subscale) showed statistically significant differences among participants receiving anastrozole versus tamoxifen and exemestane. It can be concluded that the QoL of postmenopausal women with breast cancer is affected by the long-term use of adjuvant endocrine therapy, with difference reported associated with the different therapies. However, further efforts are required to improve QoL instruments and the quantitative evaluation of QoL data for patients receiving adjuvant ET.

Keywords: Breast cancer; hormonal therapy; quality of life; women

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Key Points

- Postmenopausal women's quality of life (QoL) is affected by the long-term usage of adjuvant endocrine therapy.
- Clinicians and metastatic cancer patients need to make informed and shared decision.
- QoL of breast cancer patients improved through several simple and effective interventions.

Introduction

Breast cancer (BC) is the most frequently diagnosed and leading cause of mortality among women globally, with an average of 1.7 million newly diagnosed cases and 521,900 deaths annually, accounting for 25% of the cancer cases and 15% deaths due to cancer among women (1). Approximately 70% of all BCs are hormone-sensitive and likely respond to endocrine treatment (2). The success of endocrine therapies, modern chemotherapy, and targeted therapy indicates an increased number of metastatic BC patients receiving multiple lines of treatment. However, the cure for BC depends on complementary therapies and lifestyle changes alongside standard medical treatments to control symptoms of BC. Two of the most important objectives to improve treatment efficiency include survival prolongation and improvement in health-related quality of life (HRQoL) (3).

Over time, the diagnosis and treatment of BC has improved significantly. In addition to survival, another approach enhances the quality of life (QoL) as a significant clinical outcome. HRQoL is considered an essential endpoint in cancer clinical trials. HRQoL, a multidimensional concept, refers to a patient's subjective view of how their condition and treatment affect physical, psychological, and social components of everyday life (4, 5). Subsequently, in randomized control trials (RCTs), the evaluation of HRQoL while evaluating new treatments for BC patients is important. There is a diversity of QoL instruments used in clinical trials to capture different dimensions of QoL in metastatic BC trials, with the use of "European organization for research and treatment of life questionnaire C30 – EORTC QLQ C30", "EORTC BC

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module – EORTC QLQ BR23", MENQOL, FACT/FACIT or SF-36 used frequently. These questionnaires evaluate physical conditions and functioning domains and patient-reported evaluations of their health and QoL in cancer trials (6).

Agents that target particular molecular abnormalities seen in BC cells have the potential to improve clinical outcomes. This is demonstrated by the efficacy of trastuzumab and lapatinib in treating human epidermal growth factor receptor 2 (HER2)-overexpressing BC and everolimus coupled with endocrine treatment for hormone receptor-positive metastatic BC (7). Adjuvant therapy for BC involves using systemic treatment to eliminate any microscopic tumor cells that might remain in the body. It is given after primary therapy to increase the chance of long-term disease-free survival. These therapies include chemotherapy, endocrine therapy, the targeted drug Trastuzumab, radiation therapy, or a combination of treatments. Decisions associated with the treatments are based on the stage and type of cancer, the presence of hormonal and HER2/neu receptors, and the patient's health and preferences.

Advances in BC treatment have been made as the disease's frequency has increased. As a result, systematic assessment of survival outcomes in patients receiving anticancer therapy should include disease-free survival and overall survival (8). When it is taken as prescribed, hormonal therapy decreases the risk of BC recurrence by 40% and the mortality by a third (9). However, in spite of its clinical efficacy for preventing recurrence, a number of cancer survivors do not take the hormonal therapy as prescribed. About 50% of the women take less than 80% of the prescribed dosage (10) and almost 50% of women stop their treatment by the fifth year of the prescription (11). This leads to an increase in the recurrence and mortality of BC (12). Therefore, persistence and adherence to hormonal therapy is considered as a key determinant of disease-free survival. Adherence is described as the degree to which a person's behavior corresponds with the agreed treatment recommendations in the context of dose, frequency and timing. Persistence is defined as the duration of treatment from initiation to discontinuation (13).

Currently, research has started to explore the factors that affect adherence and persistence behavior and has identified socio-demographic, psychological and clinical aspects as the potential risk factors (14, 15). In a current review of barriers and facilitators of hormonal therapy adherence and persistence, a number of factors were identified as possible intervention targets, due to their effect on patients' persistence and adherence behavior. One of them was categorized as side effects of hormonal therapy and incorporated cognitive, gynecological, musculoskeletal and fatigue related symptoms. Also, a number of studies have found that patients experience hormonal therapy side-effects, such as joint pain, hot flushes, night sweats and fatigue, which affect adherence and rates of treatment discontinuation (14, 16, 17), potentially because the side effects of treatment outweighs the perceived benefits (18).

So, unlike socio-demographic and clinical aspects that are not easily changed, side effects are suggested intervention targets because effective management has the potential to increase long-term hormonal therapy adherence and reduce the rates of treatment discontinuation. However, the contribution of specific side effects to hormonal therapy non-adherence and non-persistence is not well understood, making the development and prioritization of targeted intervention strategies challenging. A number of studies prefer to use close-ended questionnaire to report side effects profile where the presence or absence of side effects are reported as a "yes" or "no" variable (19-21).

However, QoL has become a vital outcome metric in BC clinical investigations and survival research because disease detection and treatment have substantially improved (22, 23). There is currently a range of information on the issue, but it is challenging to identify robust evidence of optimal management in practice due to contradictory conclusions. Therefore, this review study was conducted to examine and synthesize the current data on HRQoL in BC patients. Accepting and implementing robust practices and methodologies in metastatic BC clinical trials is essential to assess patients' indications, side effects, operative activities, HRQoL, and customary clinical outcomes for progression-free and complete survival. Therefore, this study aimed to analyze the significance and impact of HRQoL of women with BC undergoing treatment with hormonal therapy.

Materials and Methods

This study developed a comprehensive, structured, and systematic search strategy to identify literature about HRQoL in BC patients undergoing treatment with hormonal therapy. The search was conducted for published literature indexed in PubMed (Medline), Cancer Lit, CINAHL, Google Scholar, and Web of Science from 2010 to 2020.

This study included patients with BC and BC patients on hormonal therapy. The study used a comprehensive evidence map search strategy of systematic reviews as described by Lunny et al. (24) The medium of language for the search was English. Search algorithms used in the databases included the following terms: "Breast cancer" or "quality of life of breast cancer patients", "hormonal therapy", "breast metastasis", "health-related quality of life", "breast carcinoma", "endocrine therapy", "antihormone therapy", "hormonal therapy", "treatment", and "therapy". In this review, the BC patient population here refers to patients having treatment eligibility during the disease course; all full articles with QoL as a significant outcome in BC patients were included. The exclusion criteria included all other languages except for English, animal studies, and articles without full text. The articles were screened as per the guidelines provided by "Preferred Reporting Items for Systemic Reviews and Meta-Analyses" (PRISMA) and the AMSTAR checklist (Figure 1) to examine the quality of publication for the included articles. Initially, 1,878 articles were screened from multiple databases. Eight articles were included in the review after the removal of either duplicate or irrelevant articles. The data were synthesized using descriptive tables, including authors' names, year of publication, sample size, age, significant findings assessing the QoL, and QoL instruments.

Results

The study initially identified 1,878 articles from multiple databases, and after the removal of duplicate articles, eight of them were included in the study for 2010 to 2020. Table 1 demonstrates the essential information and characteristics of the included studies. Out of eight shortlisted studies, seven reported clinical trials and HRQoL as their secondary result. Overall, main characteristics (mean age and QoL instruments) of the included studies were almost identical to the median follow-up time of 18 months for average research.

Three studies compared the administration of hormonal therapy versus another hormonal therapy in BC patients (12-14). Three studies used N-SAS BC 04, N-SAS BC 03, and MA-17R RCTs. In a study by Takei et al. (25) comparisons of two aromatase inhibitors (AIs) with tamoxifen and overall QoL scores rose after the initiation of treatment. In the first year, improved QoL was achieved in the tamoxifen group compared to in the aromatase inhibitors sub-group. The endocrine-related symptoms did not fluctuate between interventions and remained unchanged in all the groups. This study also used FACT-G scores to evaluate QoL globally among participants receiving anastrozole versus tamoxifen and exemestane. A statistically significant difference was observed across the groups. After treatment initiation in the tamoxifen group, FACT-G scores increased. The change of score for the tamoxifen group was four, representing no significant change over time. In this study, the N-SAS BC 04 included three arms, including two AIs and a tamoxifen group and FACT-B scores remained raised in the tamoxifen group compared to the AI group for one year. Another study by Ohsumi et al. (26) compared AIs with tamoxifen. Results showed improved total FACT-G scores in the tamoxifen group and stable scores over time; however, scores in the AI group decreased but not significantly. In addition to this, the FACT-B scores remained unchanged. The third included study was reported by Goss et al. (27) and they carried out a five-year research on AIs alone. They found that compared to letrozole plus, AIs when compared using MENQOL, had no significant impact over a time period. In all three of these studies, QOL was assessed as a secondary endpoint.

Another study by Beck et al. (28) presented the BOLERO-2 trial with two arms, arm one consisting of everolimus and exemestane and the other arm consisting of exemestane only. The results showed that better QoL was observed in the everolimus group compared to the exemestane monotherapy group, despite higher adverse events reported. Another study by Hojan et al. (29) used EORTC, QLQ-C30, and EORTC QLQ BR23 questionnaires as QoL instruments in premenopausal BC patients after using endocrine therapy that negatively affected the impact of QoL in patients. The study emphasized incorporating physical exercise to reduce endocrine therapy side effects and improve HRQoL.

Two studies by Verma et al. (30) and Harbeck et al. (31) assessed the HRQoL in premenopausal (HR+/HER-) BC patients with the use of ribociclib with letrozole in the phase III MONALEESA-2 trial in 668 patients. The study by Taira et al. (32) used phase 3 MONALEESA-7 trial to study the ribociclib and endocrine therapy combination leading to improved HRQoL in patients on RIB+ET combination. Patient-reported outcomes (PROs) were assessed using (EORTC QLQ-C30), and the BC-specific (EORTC QLQ-BR23) questionnaires, and results demonstrated consistent HRQoL scores at baseline. A better AUC curve was also observed in the ribociclib arm. The impact on HRQoL during neo-adjuvant endocrine treatment with letrozole in 497 patients with a mean age of 63 was not found significant.

Discussion and Conclusion

The results of this literature review study describe the impact on HRQoL in BC patients on endocrine treatment as well as the side effects of hormonal therapy. In a detailed review of the literature from 2010 to 2020, eight articles were shortlisted, including seven RCTs, and one was a feasibility study. For evaluation of HRQoL, the EORTC QLQ-C30, EORTC QLQ BR23, EQ-5D-5L, SF-36, MENQOL, FACT-B, FACT-ES, CES-D, and FACT- G based questionnaires for the assessment of QoL were used, respectively.

Measurements of HRQoL are usually carried out with carefully designed and validated instruments, such as questionnaires or semi-structured interviews. Reliability, validity, and responsiveness are prerequisites for an ideal PRO questionnaire (33). EORTC QLQ C30 is a 30-item questionnaire that consists of five (social, emotional, physical, cognitive, and role) functional scales followed by three symptom scales (nausea/vomiting, fatigue, and pain) and a global health status scale. Similarly, the EORTC QLQ BR23 companion module to EORTC

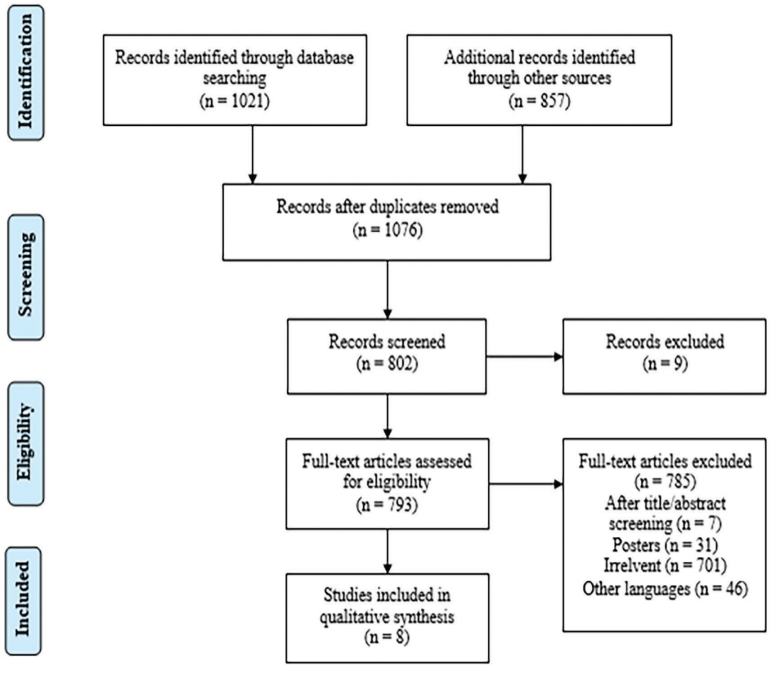

 Figure 1. PRISMA flow diagram representing the study's inclusion/exclusion criteria

Table 1. Basic information and characteristics of included studies

Study	Region	Trial name	Arms	Mean age (y)	Treatment duration (y)	QoL endpoint	QoL instruments	QoL study/ trial samples (N/N)	Main QOL findings	Clinical significance of QOL study findings	Timing of QOL measures
Takei et al. (25)	Japan	N-SAS BC 04	Arms	NA	5	Secondary	FACT-B, FACT-ES, CES-D, FACT-G	166/NR	FACT-G, FACT-G, and the FACT-ES total scores were statistically significantly better in the tamoxifen group than in the anastrozole group (p = 0.042, 0.038, and 0.005, respectively) on physical well-being subscale. Total FACT-G scores were reduced in the ANA group during one year and continued until two years; however, tamoxifen group scores were generally steady.	Yes	BL, 3 and 12 mo.
Ohsumi et al. (26)	Japan	N-SAS BC 03	TAM vs. EXE vs. ANA	63	5	Secondary	FACT-B, FACT-ES, CES-D, FACT- G	694/NR	After treatment initiation, raised FACT-G and BCS scores were recorded in the tamoxifen group. FACT-B scores increased after treatment began and remained significantly higher in the tamoxifen group than in the exemestane or anastrozole groups for one year (p = 0.045). ES scores were largely unchanged in all three treatment groups, and there was no significant difference between any groups (p = 0.36). In all patients assigned to exemestane or tamoxifen, FACT-B scores increased after treatment began and remained significantly higher in the tamoxifen group than in the exemestane group for one year (p = 0.047)	Yes	BL, 3 mo, 1 and 2 y
Goss et al. (27)	Canada, USA	MA-17R	1–4 y TAM → ANA vs. TAM	65.1	10	Secondary	SF-36, MENQOL	1630/1918	No statistically significant between-group differences were observed in the SF-36 summary scores on any of the four MENQOL symptom subscales	Yes	BL and 12, 24, 36, 48, and 60 mo
Beck et al. (28)		BOLERO-2	5 y AI + 5 y LET vs. 5 y AI + PL	62	1	secondary	EORTC QLQ C30	100/37	BOLERO-2 trial used two arms, the advantage of EVE to EXE detected in patient's subsections whose disease progressed during or after (neo) adjuvant NSAI therapy was steady with that observed in the overall population. Furthermore, the considerable advancement in PFS in this subset was achieved while sustaining HRQoL.	Yes	

Table 1. Continued

Study	Region	Trial name	Arms	Mean age (y)	Treatment duration (y)	QoL endpoint	QoL instruments	QoL study/ trial samples (N/N)	Main QOL findings	Clinical significance of QOL study findings	Timing of QOL measures
Hojan et al. (29)	Poland	feasibility study	EVE + EXE vs. EXE	41	3	Secondary	EORTC, QLQ-C30, EORTC QLQ BR23	41	ET negatively impacts premenopausal breast cancer patients' body composition, physique, and QoL. This feasibility study shows that physical activity may improve QoL and reduce adverse effects of ET on body composition and body physique, indicating appropriateness for further investigation on the use of exercise programs in premenopausal breast cancer patients to improve therapy outcomes.	Yes	
Verma et al. (30)		MONALEESA-2	GOS + TAM	62	1	Secondary	EORTC QLQ-C30, EORTC QLQ BR23	668	HRQoL was consistently maintained from baseline in postmenopausal women with HR+, HER2– advanced breast cancer receiving ribociclib plus letrozole and was similar to that observed in the placebo plus letrozole arm. Together with the improved clinical efficacy and manageable safety profile, these PRO results provide additional support for the benefit of ribociclib plus letrozole in this patient population.	Yes	
Harbeck et al. (31)		MONALEESA-7	RIB? LET vs. LET	40-49	1	Secondary	EORTC QLQ-C30, EQ-5D-5L	335/337	HRQoL was maintained longer in patients who received ribociclib + ET versus placebo + ET. Combined with previously reported improvements in PFS and OS, these data support a strong clinical benefit-to-risk ratio with ribociclib-based treatment in pre-and premenopausal patients with HR+/HER2– ABC.	Yes	
Taira et al. (32)		NEOS	RIB + ET	63	3	Secondary		497	Neoadjuvant endocrine therapy with LET had no impact on global HRQoL but influenced endocrine-related symptoms such as hot flush.	Yes	

GOS: goserelin; TAM: tamoxifen; EVE: everolimus; EXE: exemestane; LET: letrozole; AI: aromatase inhibitors; ANA: anastrozole; PL: placebo; QOL: quality of life; RIB: ribociclib; ET: endocrine therapy

QLQ C30 is BC-specific. It comprises four functional parameters (future perspective, body image, sexual functioning, and sexual enjoyment) followed by four symptom parameters (systemic therapy, arm, breast, and hair loss) (34-36).

The present study used the phase 3 MONALEESA-7 trial to study the ribociclib and endocrine therapy combination, leading to improved HRQoL in patients on RIB+ET combination.

Similarly, another study was conducted by van Nes et al. (37) to assess the QoL in the Tamoxifen, Exemestane Adjuvant Multinational (TEAM) Trial following its comparison with the adverse effects given in the central database. Dutch postmenopausal early BC patients participated in the QoL side study and completed questionnaires at 1 (T1) and 2 (T2) years after the start of ET. Questionnaires comprised the EORTC QLQ-C30 and BR23, supplemented with FACT-ES. Five hundred and forty-three patients completed questionnaires at T1 and 454 patients (84%) at T2. Overall, QoL and most functioning scales improved over time. The only clinically relevant and statistically significant difference between treatments was related to insomnia, as exemestane-treated patients reported more insomnia (38). Patients associated with the study of QoL felt some difficulties in terms of depression, anxiety, chronic fatigue, sleep problems, pain, sexual dysfunction and sleep disorders. At the same time, more adverse events were observed in patients in Tamoxifen Exemestane Adjuvant Multinational (TEAM) trial database. Not to overlook the advantages of hormonal therapy in decreasing the risk of recurrence of BC and mortality rate, it has been found that a number of cancer survivors do not take the prescribed hormonal therapy and it has been reported in one of the studies (10) that almost 80% of women take less than 80% of the prescribed dosage and 50% stop their treatment by the fifth year of the prescription (11) thus leading to an increase in the recurrence and mortality of BC (12). This is why persistence and adherence to the treatment of hormonal therapy is considered as some of the key determinants of disease-free survival (13).

It is important to remember that this evaluation of reviews has certain limitations. The key criticism is that it is impossible to generalize the results because only eight evaluations with varying agendas were examined. It is important to remember that this review is a bibliometric analysis of review articles and represents what has been accomplished over the previous decade in reviewing the QoL in BC patients. It appears that additional targeted and in-depth studies are needed. It is believed that this review might show repetition and disparities, and places that require further effort. For example, no particular reviews on the QoL in BC survivors were found, although the studies included both BC patients and survivors. Perhaps a further and intense investigation is needed to address independently considering differences in QoL between newly diagnosed patients, long-term survivors who have completed their treatments, and patients receiving different treatments. BC survival is a highly significant and relevant issue that demands more attention. Finally, it is possible that some of the publications were overlooked entirely as the method in this study was confined to using minimum key phrases to search for relevant articles.

The current review reports that the QoL in BC patients has improved dramatically in recent years, due to various basic but effective therapies, such as hormonal therapy. The current study found, however, that symptoms generated by different treatment methods are still underestimated and require more careful consideration. The study concluded that the QoL of postmenopausal women is affected by the long-term use of adjuvant endocrine therapy. However, further efforts are required to complement QoL instruments and the QoL data reporting quantitative evaluation of QoL for patients receiving adjuvant ET and, consequently, enable clinicians and metastatic cancer patients to make an informed and shared decision. The QoL of BC patients has been improved significantly through several simple and effective interventions.

Nonetheless, symptoms due to various treatment modalities are still under observation. Clinical outcomes in severe patients can be enhanced by incorporating interventions aimed at improving HRQoL, especially in patients receiving endocrine or hormonal therapy. More research on social support strategies in Asian settings is required to uncover effective ways to enhance patients' HRQoL.

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Peer-review: Externally peer-reviewed.

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