Evaluation of the clinical effect of pharmacist intervention

Results of patient education about breast cancer

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Abstract

Introduction: Breast cancer is one of the most common cancers among Egyptian women. Health-related quality of life (QOL) and reduction of side-effects play an important role for the treatment of cancer patients. The purpose of this prospective study was to determine if pharmacist’s intervention could improve clinical outcomes of patients with breast cancer.

Patients and methods: This study was a single-center interventional prospective study carried out on a group of 60 breast cancer patients at Clinical Oncology Department, Ain Shams University Hospitals from June 2017 to May 2018 patients were subjected to a thorough history taking, assessment of treatment-related adverse events before each cycle and at the end of the treatment. In addition, assessment of QOL was done at the baseline and at the end of treatment to evaluate the effect of the pharmacist’s interventions.

Results: The present study has shown that the clinical pharmacist interventions were associated with significant decrease of toxicity grades of patients, for example, anemia where the percentage of patients of grade 2 decreased from 17% to 1.7%; moreover, 5% of patients had grade 4 nausea/vomiting, while after pharmacist intervention, it became 0%. Regarding patients’ QOL, results of the present study showed improvement of mean ± standard deviation of most of the QOL scales such as systematic therapy side-effects decreased from 80.8 ± 19.53 to 42.8 ± 16.8, all with P < 0.001.

Conclusions: Most treatments for breast cancer despite beneficial result in toxicities, primarily anemia, neutropenia, nausea, and pain. These side-effects adversely impact patient QOL and can lead to treatment discontinuation. Clinical pharmacist intervention resulted in beneficial clinical outcomes in patients with breast cancer such as the reduction of treatment-related side-effects and the improvement of patients’ QOL.

Abbreviations: QOL = quality of life; SD = standard deviation; SPSS = Statistical Package for Social Sciences.

Keywords: breast cancer, clinical pharmacist interventions, quality of life, toxicity grades.

1. Introduction

Breast cancer (BC) is one of the most common malignancies in women worldwide. Currently, breast cancer incidence in Europe is 94.3 per 100,000, with a mortality of 26 per 100,000. BC accounts for one-third of cancers diagnosed in women in the United States and is the second leading cause of cancer death worldwide. BC accounts for one-third of cancers diagnosed in women in the United States and is the second leading cause of cancer death worldwide.

The increased survival of breast cancer patients, the younger age at diagnosis, and the more focus should be taken on quality of life (QOL) to both healthcare providers and patients. Previous evidence has indicated that breast cancer patients may not show obvious evidence of disease, but they do suffer from a number of problems which persist long after initial treatment, such as physical problems (pain and fatigue), psychosocial problems (fear of recurrence and inability to cope with the disease), and psychosocial problems (family worries and sexual problems). Therefore, there is a great need to provide education, information, and support over time.

QOL is the appropriate one of the main determinants of treatment success in modern oncology. QOL related to health is now considered as an important parameter in clinical cancer trials. It has been shown that QOL assessment in cancer patients help improve treatment and may even be one of the prognostic factors. To assess QOL, multiple scales can be used. In oncology, the questionnaire on the QOL of the European Organization for Research and Treatment of Cancer (EORTC)-specific module of the breast QLQ-BR23 is the most useful probably because it is reliable, simple, available and easy to answer, and validated in several European languages.

Also, QOL measurement instruments have been widely used in many global tests. Studies indicate that the scales of QOL provide sociodemographic and clinical measures and also can help predict survival in patients with breast cancer. Despite this, few studies have investigated prospectively the QOL of patients with breast cancer using standardized and validated instruments.

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The objective of this study was to evaluate the impact of pharmacist’s educational interventions on health benefits and QOL of patient with breast cancer.

2. Methods

2.1. Subjects and study design

This is an interventional prospective single-arm study on QOL of breast cancer patients. A total of 60 patients of breast cancer were collected from the Clinical Oncology and Nuclear Medicine Department, Ain-Shams University Hospitals during 2017–2018.

Patients were recruited during the period of August 2017—January 2018. They were followed for 6 months to assess changes in their QOL. This follow-up was done at baseline and after 6 months of their inclusion in the study. All patients subjected to baseline of therapy to data collection (demographic data, evaluation of risk factors, and also assessing QOL) then pharmacists’ intervention for patient counseling [nature of the disease, expected chemotherapy side-effects, optimal dietary regimen, and medication therapy management (adherence to medication regimen, detecting any drug–drug, drug–disease, or drug–food interactions)], assessing health-related QOL after 6 months at the end of the study period. They were included in the study with any type of treatment as determined by their physicians. The survey was conducted by using the assessment of QOL questionnaire EORTC QLQ-BR23.

The content of educational programs included basic information regarding breast cancer facts and figures, breast cancer epidemiology, breast anatomy, risk factors of breast cancer development, signs and symptoms, important early detection, recommended screening methods, guidelines for mammography screening, role of mammography in early diagnosis breast cancer, and presentation list of governmental hospital where can get mammography. In addition to this information, each group received specific messages related to health motivation, susceptibility to breast cancer, the perceived benefits and barriers of mammography, and perceived self-efficacy based on HBM.

2.2. Measure

Arabic version of the questionnaire EORTC QLQ-BR23 has been validated to assess QOL in patients with cancer and particularly in patients suffering from breast cancer in our study.

EORTC QLQ-BR23, breast cancer-specific questionnaire, consists of 23 items divided between a functional dimension scales including body image, sexual functioning, sexual enjoyment, and future prospects and a symptom dimension consists of systemic therapy scales, side-effects, breast symptoms, hands, and hair-loss symptoms.

According to the guidelines of the EORTC, scores on the items were converted to a scale of 0–100. A high score for a functional scale represents a healthy level of functioning, but a high score on a scale of postsymptoms represents a high level of symptomatology.19

3. Ethics approval

The study protocol was approved and designed according to the Ethical Guideline of Faculty of Pharmacy, Ain-Shams University (Approval No. 2017-156) and was conducted with all applicable ethical standards. Before participation, all patients were educated about the study protocol and signed written informed consent.

4. Data analysis

- Data were managed with Statistical Package for Social Sciences (SPSS) version 20 for windows.
- Data were checked for accuracy of data entry and missing values.
- Quantitative data were presented as mean, standard deviation (SD), and range values.
- Paired t-test was done for comparing quantitative variables between before and after in 1 group and P-value ≤ 0.05 was considered significant.
- Qualitative data were expressed as frequencies (n) and percentage (%).
- McNemar test and Wilcoxon matched-pair signed-rank test were used for comparing before and after in qualitative-ranked variables (variables had ranked grades), and P-value ≤ 0.05 was considered significant.
- For the assessment of the QOL, the Student’s t test for the comparison of means paired data was used to search for the possible existence of differences in life of quality between the different parameters in the 1st and 12th month for each scale EORTC-C30 and EORTC-BR23. Data were analyzed using SPSS Version 20.0 software.

5. Results

5.1. Patients’ characteristics

A total of 60 patients participated into our study and completed the questionnaires. These patients were assigned into 1 group who received pharmacist’s intervention using patient-counseling tools.

The demographic and clinical characteristics of included population are shown in Table 1. One group consists of 60 females (100%) of mean age 55.3 ± 11.7 years with an age range of 33–83 years. Majority of patients were at clinical stage I and II at the time of diagnosis, with a proportion of 25.0% and 55.0%, respectively. Local advanced BC was the most common diagnosis (65.0%), and almost all patients received chemotherapy and hormone therapy.

| Parameter | Patients (n = 60) |
|-----------|------------------|
| Age mean ± SD (range) | 55.3 ± 11.7 (33.0–83.0) |
| Weight mean ± SD (range) | 81.6 ± 12.6 (50.0–115.0) |
| Height mean ± SD (range) | 160.2 ± 4.3 (149.0–170.0) |
| Side (n %) | |
| Left | 26 (43.3%) |
| Right | 26 (43.3%) |
| Bilateral | 8 (13.3%) |
| Diagnosis type (n %) | |
| Early diagnosed BC | 14 (23.3%) |
| Local advanced BC | 39 (65.0%) |
| Metastasis BC | 7 (11.7%) |
| Stage (n %) | |
| Stage I | 15 (25.0%) |
| Stage II | 33 (55.0%) |
| Stage III | 5 (8.3%) |
| Stage IV | 7 (11.7%) |

BC = Breast cancer; SD = standard deviation.
5.2. Adverse events

Treatment-related adverse events were assessed by the clinical pharmacist using the NCI-CTCAE v4.03 before each cycle. The most common higher adverse events were anemia, neutropenia, and thrombocytopenia and mucositis was managed accordingly.

No dose reduction was required for any patients. The toxicity profiles of the used regimens were listed in Tables 2 and 3, where the present study has shown that the clinical pharmacist interventions were associated with significant decrease of toxicity grades of patients, for example, anemia where the percentage of patients of grade 2 decreased from 17% to 1.7%, while patients having neutropenia grade 4 decreased from 10% to 0%; moreover, 5% of patients had grade 4 nausea/vomiting, while after pharmacist intervention, it became 0%.

5.3. Breast cancer-specific scores

Breast cancer patients’ QOL scores as measured by the EORTC QLQ-BR23 are shown in Tables 4 and 5, where change in QOL was assessed at the 1st and 6 months. Different parameters of EORTC QLQ-BR23 questionnaire were evaluated, the present study showed improvement of mean ± SD of most of the QOL scales such as body image from 25.3 ± 20.2 to 61.6 ± 16.8 and future prospects from 17.2 ± 18.9 to 58.9 ± 15.5.

Sexual functioning which had a high score in the first months slightly worsened at 6 months (80.0 versus 72.8, P < 0.001); It is also the same for sexual enjoyment (81.7 versus 70.6, P < 0.001).

For the symptoms dimension, significant improvements were observed for symtoms of breast symptoms and arms where systematic therapy side-effects decreased from 80.8 ± 19.53 to 42.8 ± 16.8, breast symptoms decreased from 79.9 ± 18.6 to 49.8 ± 82.4, all with P < 0.001.

Table 2: Hematologic toxicity grades’ changes before and after pharmacists’ intervention.

|               | n  | %   |
|---------------|----|-----|
| Anemia_before | 1  | 42  | 79.2|
| 2             | 9  | 17.0|
| 3             | 1  | 1.9 |
| 4             | 1  | 1.9 |
| Anemia_after  | 1  | 58  | 96.7|
| 2             | 1  | 1.7 |
| 3             | 1  | 1.7 |
| Neutropenia_before | 1  | 8  | 13.3|
| 2             | 26 | 43.3|
| 3             | 20 | 33.3|
| 4             | 6  | 10.0|
| Neutropenia_after | 1  | 33 | 55.0|
| 2             | 21 | 35.0|
| 3             | 6  | 10.0|
| Thrombo_before | 1  | 49 | 81.7|
| 2             | 11 | 18.3|
| Thrombo_after  | 1  | 59 | 98.3|
| 2             | 1  | 1.7 |

Table 3: Nonhematologic toxicity grades’ changes before and after pharmacists’ intervention.

|               | n  | %   |
|---------------|----|-----|
| N_V_before    | 2  | 26  | 43.3|
| 3             | 31 | 51.7|
| 4             | 3  | 5   |
| N_V_after     | 1  | 25  | 41.7|
| 2             | 33 | 55  |
| 3             | 2  | 3.3 |
| Mucostis_before | 2  | 27 | 45  |
| 3             | 30 | 50  |
| 4             | 3  | 5   |
| Mucostis_after | 1  | 29  | 48.3|
| 2             | 28 | 46.7|
| 3             | 3  | 5   |

6. Discussion

This study allowed us to assess QOL in patients with breast cancer. All patients were included in a study of their type of treatment as determined by their physician. The monitoring was done over 6 months with Arabic dialect version EORTC QLQ-BR23 validated and standardized questionnaire.

Analysis of functional dimensions of the EORTC QLQ-BR23 revealed a significant improvement in QOL on the scales of body image and future perspective.

These results are consistent with those reported by David et al.[11] However, Liu et al.[12] reported deterioration in the QOL for body image and future perspective after a year of follow-up. Sexual function and sexual enjoyment that had high scores have worsened during follow-up. Previously, David et al.[11] found cases of deterioration in the QOL for sexual function and no significant change in sexual enjoyment.

Previous studies by Hill et al.[13,14] have reported a high rate of sexuality concerns in breast cancer survivors. The reasons might be lack of physical attractiveness after breast surgery and other somatic problems such as vaginal dryness caused by chemotherapy.

Regarding the size of the symptoms of EORTC QLQ-BR23, there was a significant improvement in symptoms in the arms and

Table 4: Comparison of mean of functional scales scores of patients in the study group before and after pharmacists’ intervention.

|               | Mean ± SD | Minimum | Maximum | Paired t-test | P     |
|---------------|-----------|---------|---------|--------------|-------|
| Sexual function | Before 79.996 ± 19.60330 | 33.3 | 100 | 2.706 | 0.009* |
| After 72.7745 ± 25.86174 | 33.3 | 100 | | | |
| Body image | Before 25.2753 ± 20.23483 | 66.7 | −23.339 | 0.000* |
| After 61.6612 ± 16.89083 | 33.3 | 100 | | | |
| Sexual enjoyment | Before 81.6637 ± 20.74673 | 33.3 | 100 | 3.793 | 0.000* |
| After 70.5923 ± 26.81733 | 33.3 | 100 | | | |
| Future perspective | Before 17.2205 ± 18.90582 | 66.7 | −20.432 | 0.000* |
| After 58.8832 ± 15.48435 | 33.3 | 100 | | | |

Wilcoxon matched-pair signed-rank test; SD = standard deviation.
*Indicates significance.
breasts during follow-up. David et al[11] found a significant improvement in all symptoms of EORTC QLQ-C23 during follow-up.

After this study, we could demonstrate a significant overall improvement in the QOL of patients with breast cancer after 6 months of follow-up regarding functional scales and symptom scales for the specific EORTC QLQ-BR23 questionnaire of breast cancer, there was observed a slight deterioration of the QOL concerning sexual function and sexual enjoyment for functional scale.

7. Conclusions

This study has shown that the evaluation of the QOL through clinical pharmacists’ interventions resulted in beneficial clinical outcomes in patients with breast cancer such as the reduction of treatment-related side-effects and the improvement of patients QOL.

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Table 5

Comparison of mean of symptom scales scores of patients in the study group before and after pharmacists’ intervention.

|                      | Mean ± SD | Minimum | Maximum | Paired t-test | P |
|----------------------|-----------|---------|---------|--------------|---|
| Upset hair loss      |           |         |         |              |   |
| Before               | 82.7742 ± 18.91194 | 33.3    | 100.0   | 2.489        | <0.0001* |
| After                | 43.3290 ± 17.67923  |         | 66.7    |              |   |
| Systematic therapy side-effects |          |         |         |              |   |
| Before               | 80.8713 ± 19.53678  | 33      | 100     | 19.657       | <0.0001* |
| After                | 42.8392 ± 16.81459  |         | 66.7    |              |   |
| Breast symptoms      |           |         |         |              |   |
| Before               | 79.9696 ± 18.61781  | 33      | 100     | 2.937        | <0.005*  |
| After                | 49.8567 ± 82.49787  |         | 66.7    |              |   |
| Arms symptoms        |           |         |         |              |   |
| Before               | 79.9965 ± 19.60324  | 33      | 100     | 22.049       | <0.001*  |
| After                | 40.3627 ± 16.49138  |         | 66.7    |              |   |

Wilcoxon matched-pair signed-rank test; SD = standard deviation.

* Indicates significance.