Feasibility of quality of life assessment in routine clinical oncology practice: a Tunisian study

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ABSTRACT Limited research has been devoted to quality of life (QOL) of cancer patients in developing countries. To assess the feasibility of QOL assessment in a cohort of Tunisian cancer patients, the EORTC QLQ-C30 questionnaire was administered to 23 women treated with adjuvant chemotherapy for early breast cancer on an outpatient basis at baseline and during the 3rd cycle of chemotherapy. We observed a significant deterioration in physical functioning, cognitive functioning and social functioning during chemotherapy. However, a wide range of methodological and practical obstacles to routine QOL evaluation were identified through this study. Further improvement of cancer care infrastructure and public education is still needed before reliable QOL studies can be performed.

Faisabilité d’une évaluation de la qualité de vie dans la pratique clinique de routine en oncologie : une étude tunisienne

RÉSUMÉ La recherche consacrée à la qualité de vie des patients cancéreux dans les pays en développement est limitée. Afin d’estimer la faisabilité d’une évaluation de la qualité de vie dans une cohorte de patients cancéreux tunisiens, nous avons présenté le questionnaire QLQ-C30 de l’EORTC à 23 femmes traitées par chimiothérapie adjuvante en ambulatoire pour un cancer du sein à un stade précoce, au début du traitement et pendant le troisième cycle de chimiothérapie. Nous avons observé une détérioration significative des performances physiques, cognitives et sociales pendant la chimiothérapie. Toutefois, cette étude a permis de recenser de nombreux obstacles méthodologiques et pratiques à l’évaluation de la qualité de vie dans les traitements de routine. Il est nécessaire d’améliorer encore l’infrastructure de soins et la sensibilisation du public en matière de cancer si l’on veut réaliser des études fiables sur la qualité de vie des cancéreux.
Introduction

Since the early 1980s, a large body of oncology research has been devoted to assessment of quality of life (QOL). However, until now this research remains largely confined to developed countries. Although cancer incidence is increasing in the developing world [1], few studies have examined QOL issues for cancer patients in these areas.

The impact of breast cancer therapy on patients’ QOL has been extensively studied in the literature [2,3]. In Tunisia, this disease is the most frequently diagnosed neoplasm in women, with an estimated age-standardized incidence of 27 per 100 000 women [4]. In the southern region, which is served by our department, approximately two-thirds of breast cancer patients present with operable tumours, while locally advanced and metastatic disease represent 23% and 12% of cases respectively [5]. Nonetheless, most patients with operable disease have large tumours and/or histologically proven axillary lymph node involvement requiring adjuvant cytotoxic chemotherapy. Such treatment is frequently associated with both immediate and long-term adverse effects which significantly affect patients’ QOL.

The objective of the present study was to assess the feasibility of QOL evaluation in a cohort of Tunisian women with early breast cancer receiving adjuvant chemotherapy.

Methods

Between June and August 2000, we recruited all patients with a diagnosis of operable breast cancer who were referred to the Department of Medical Oncology in Sfax University Hospital for adjuvant chemotherapy. Patients had to have a T1-3N0-1M0 invasive breast cancer [6] treated with primary surgery (radical or segmental mastectomy with axillary lymph node dissection).

We recorded the following data: age, marital status, level of education, employment status, performance status (World Health Organization scale), clinical tumour size, type of primary surgery, histological tumour size, hormone receptor status, number of positive axillary lymph nodes and chemotherapy regimen.

QOL was evaluated using the Arabic version of the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 questionnaire [7]. QLQ-C30 is a validated, brief, self-reporting, cancer-specific measure of QOL and is composed of 5 multi-item scales that evaluate physical, role, emotional, cognitive and social functioning and 1 global health status/QOL scale. A further 3 multi-item symptom scales measure fatigue, pain and nausea/vomiting, and 6 single items assess other symptoms (dyspnoea, insomnia, appetite loss, constipation and diarrhoea) and financial difficulties. Depending on each patient’s education level, the questionnaire was either self-completed or administered as an interview.

We assessed the acceptability of the questionnaire by estimating the rate of missing items for the pre-treatment (baseline) and on-treatment questionnaire.

The QLQ-C30 was assessed by the same physician (A.M.) at 2 points of time: just prior to the start of adjuvant chemotherapy; and during the 3rd cycle of chemotherapy.

We also studied the frequency of adverse effects related to chemotherapy as evaluated by the QLQ-C30 in comparison with the physician’s standard evaluation in routine visits before each cycle.

The scoring of the EORTC QLQ-C30 items was performed according to the EORTC scoring manual [8]. Statistical analysis was carried out using the Student t-test, with statistical significance set at the 5% level (P < 0.05).
Results

Patients’ characteristics
The study included 23 patients. All were female and 82% were married. The mean age was 48 years, range 35–65 years. Fourteen (61%) patients were illiterate and 16 (70%) were unemployed. Their main clinical and pathological characteristics are shown in Table 1.

Surgery consisted of a modified radical mastectomy for 20 (87%) patients and breast-conserving surgery for the remaining 3. The median interval between surgery and the start of chemotherapy was 18 days.

Chemotherapy consisted of fluorouracil, epirubicin and cyclophosphamide (FEC regimen), administered at 3-week intervals for a total of 6 cycles. All patients received methylprednisolone and ondansetron as premedication to prevent nausea and vomiting.

Questionnaire acceptability
The questionnaire was administered as an interview to the 14 illiterate women in the sample. The non-response rate was 4% for the pre-treatment questionnaire and 6% for the on-treatment questionnaire. For both questionnaires, 12 patients (52%) did not answer item number 7 (Were you limited in pursuing your hobbies or other leisure time activities?) because they found it difficult to answer (6 patients) or because they had no activities other than housekeeping (5 patients) or for unknown reasons (1 patient). For the rest of the questionnaire, missing data were uncommon.

QOL data
Changes in QOL scores are summarized in Table 2. We observed a significant deterioration in physical ($P = 0.004$), cognitive ($P = 0.007$) and social functioning ($P = 0.012$) between the pre-treatment and on-treatment assessments, but not in global QOL, symptoms and financial difficulties. We also found no significant changes for symptom scores.

Assessment of chemotherapy adverse effects
Comparison of the physician’s assessment with the findings of the questionnaire is shown in Table 3. Except for fatigue, chemotherapy-related adverse effects were more frequently reported in routine evalu-
in the form of an interview because of the expected high rate of illiteracy among the study population. In fact, this rate (61%) was comparable to the literacy rate in Tunisian adult females aged 45–54 years, which is estimated at 50.9% [9]. Although this mode of administration produces fewer missing items, it is time-consuming for the health care team and may lead to overly optimistic data [10]. Moreover, in the context of a busy outpatient clinic, privacy and quietness were not uniformly assured, which made conditions under which questionnaires were completed suboptimal [11].

Whereas nausea and vomiting were frequently noted as side-effects during pretreatment visits, these were documented by QOL assessment in only 17% of the cases. This discrepancy may be attributable to the timing of the on-treatment QOL evaluation, which did not correspond to

<table>
<thead>
<tr>
<th>Item</th>
<th>Pre-chemo</th>
<th>During chemo</th>
<th>Mean</th>
<th>P-value</th>
<th>Clinically meaningful change (% of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global health status/QOL</td>
<td>72.5</td>
<td>68.5</td>
<td>−4.0</td>
<td>NS</td>
<td>4 69 26</td>
</tr>
<tr>
<td>Physical functioning</td>
<td>82.3</td>
<td>74.5</td>
<td>−7.8</td>
<td>0.004</td>
<td>13 52 35</td>
</tr>
<tr>
<td>Role functioning</td>
<td>63.7</td>
<td>73.9</td>
<td>+10.2</td>
<td>NS</td>
<td>52 26 22</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td>69.5</td>
<td>65.9</td>
<td>−3.6</td>
<td>NS</td>
<td>22 43 35</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td>85.5</td>
<td>75.3</td>
<td>−10.2</td>
<td>0.007</td>
<td>4 56 39</td>
</tr>
<tr>
<td>Social functioning</td>
<td>89.1</td>
<td>79.0</td>
<td>−10.1</td>
<td>0.012</td>
<td>4 61 35</td>
</tr>
<tr>
<td>Fatigue</td>
<td>25.4</td>
<td>30.7</td>
<td>+5.3</td>
<td>NS</td>
<td>26 52 22</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>8.0</td>
<td>7.9</td>
<td>−0.1</td>
<td>NS</td>
<td>22 56 22</td>
</tr>
<tr>
<td>Pain</td>
<td>26.8</td>
<td>26.1</td>
<td>−0.7</td>
<td>NS</td>
<td>26 48 26</td>
</tr>
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<td>Dyspnoea</td>
<td>17.3</td>
<td>18.8</td>
<td>+1.5</td>
<td>NS</td>
<td>4 91 4</td>
</tr>
<tr>
<td>Insomnia</td>
<td>27.5</td>
<td>18.7</td>
<td>−8.8</td>
<td>NS</td>
<td>4 83 13</td>
</tr>
<tr>
<td>Appetite loss</td>
<td>18.7</td>
<td>14.4</td>
<td>−4.3</td>
<td>NS</td>
<td>13 74 13</td>
</tr>
<tr>
<td>Constipation</td>
<td>13.0</td>
<td>4.3</td>
<td>−8.7</td>
<td>NS</td>
<td>17 74 9</td>
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<td>Diarrhoea</td>
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<td>NS</td>
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<tr>
<td>Financial difficulties</td>
<td>27.5</td>
<td>23.1</td>
<td>−4.4</td>
<td>NS</td>
<td>13 74 13</td>
</tr>
</tbody>
</table>

+ve = improvement; –ve = impairment.
Chemo = chemotherapy; NS = not significant.

Discussion

In this study, the Arabic version of the QLQ-C30 questionnaire appeared suitable to assess QOL in this cohort of breast cancer patients. For interviewed patients, the questionnaires were administered by the same physician throughout the study, which eliminated inter-observer variability. However, we found at least 3 limitations that should be discussed. These were related to: methodology, particularly the mode and conditions of questionnaire administration; underestimation of chemotherapy toxicity; and lack of assessment of the impact of surgery on QOL.

We frequently administered the QLQ-C30, which is a self-reported instrument,
the peak of chemotherapy-related toxicity [12]. Because of limited possibilities for performing telephone interviews, we could not assess QOL during the interval between routine visits, which resulted in underestimation of the impact of chemotherapy on patients’ QOL. Moreover, adverse effects such as mucositis or alopecia are not evaluated by the QLQ-C30, making physicians’ assessment more accurate than the QOL questionnaire in this respect.

The majority of our patients underwent radical mastectomy without reconstruction. Unfortunately, women referred to our centre for breast cancer usually presented with advanced stage disease. In our experience, tumours smaller than 2 cm, including non-palpable lesions, account for only 3.5% of the cases, compared with 58%, 17% and 21% for T2, T3 and T4 tumours, respectively (Masmoudi A and Frikha M, unpublished data). However, this stage distribution does not necessarily reflect the overall situation of breast cancer in our region. Patients referred to public hospitals tend to have lower education and awareness and lower socioeconomic status than their counterparts treated in private practice. As a result, they are less likely to be rapidly evaluated when early symptoms arise.

Although a meta-analysis has shown a small advantage for breast-conserving surgery over mastectomy when comparing QOL after surgery [13], no major differences have been reported in individual studies [14–16]. However, it has been generally observed that women having breast-conserving surgery report fewer difficulties with body image and clothing [17–19]. In the current study, we did not assess aspects of QOL of a personal nature, such as body image or sexuality. These subjects, often censured in Arab and Islamic societies, would not be adequately assessed unless a self-completed instrument, such as the BR-23 module, was used [20]. Unfortunately, widespread illiteracy precluded performing such a study.

Only a few studies have been performed in developing countries to assess QOL in patients with breast cancer. As in the present study, these reports suffered from serious methodological difficulties. For instance, some authors simply converted a self-administered questionnaire to an interview-based questionnaire [21,22] or excluded questions for which “a response was not expected” [21]. Another group administered the QLQ-C30 questionnaire before each cycle of adjuvant chemotherapy in 2 groups of breast cancer patients [23]. Not only, as in our study, was the timing of QOL assessment suboptimal, but the usefulness of repeating the QOL assessment during 6 consecutive visits was questionable. Moreover, the authors failed to mention the mode of administration and the proportion of women who needed assistance to complete the questionnaire.

In conclusion, QOL assessment in the context of a resource-constrained health system is clearly facing serious practical and methodological obstacles. This is in contrast to developed countries, where computer touch-screen methods have recently been

| Table 3 Frequency of chemotherapy-related adverse effects in 23 breast cancer patients comparing the physician’s assessment on routine visits and the quality of life questionnaire (QOL quest) scores |
|---------------------------------|-----------------|-----------------|
| Adverse effect                  | Physician’s assessmenta | QOL quest        |
| Fatigue                         | 78               | 78              |
| Nausea/vomiting                 | 82               | 17              |
| Appetite loss                   | 69               | 35              |
| Taste changes                   | 33               | –               |
| Mucositis                       | 69               | –               |
| Alopecia                        | 61               | –               |

a% of patients. – = not assessed
introduced to facilitate collecting QOL data from patients [24]. We must acknowledge, however, that there has been major progress in delivering cancer care in many emerging countries such as ours. Nonetheless, there is still a need for better resource allocation, infrastructure improvement and public education in order to promote early detection and improve patient care and outcome. It is only in this context that well-designed QOL studies aimed to tailor medical and psychosocial interventions can be performed.

References


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