

Quality of life management

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POSTER

Quality of sexual life in women with breast cancer and their spouses

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Purpose: To study the impact of breast cancer on sexual life.

Methods: For better exploring this area, 78 women with breast cancer, 40.3 ± 12.4 years old, filled out a questionnaire aimed at describing sexual disorders after breast cancer and estimating the sexual functioning of the couple. The study took place ≤ 1 year after the diagnosis of breast cancer for 13 patients and > 1 year for 65. Sixty-two spouses participated in the study.

Results: No significant change in the frequency of sexual intercourse was noted after the diagnosis of breast cancer; however, older patients were significantly more impaired. About 43% of patients noted a decrease in their partner's sexual interest.

Sexual life was considered important by 84% of patients and 79% spouses. Patients worried more than their spouses about medication interference; meanwhile, their spouses were more concerned about the health problem than the sexual intercourse.

On the basis of 12 shared items we computed a Quality of Sexual Life score (Cronbach's $\alpha = 0.8$). There was a high reliability between the two partner's assessments ($r = 0.73$), even though spouses' scores were significantly higher ($p = 0.02$). Quality of Sexual Life was lower in women with breast cancer since more than 1 year.

Conclusion: These results confirm the impact of breast cancer on Quality of Sexual Life and enlighten specific sexual concerns in each partner of a couple.

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POSTER

The development and utilisation of the EORTC Quality of Life item bank

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Purpose: The EORTC Quality of Life Group has developed a modular approach to assessing patients' Quality of Life (QL) in cancer clinical trials. Based on this approach, a number of modules specific to tumor sites, treatment modalities or QL dimensions not included in the EORTC QLQ-C30 have been developed to be administered with the EORTC QLQ-C30. The number of EORTC modules has rapidly increased, resulting in a degree of overlap between items and their numerous translations. In addition, we have seen an increasing demand for trial specific but validated items, a demand, which could not be met with the present module development process.

Methods: A computerized database of all existing EORTC items and translations was developed. This aimed to improve the quality and the speed of development as well as translations of new modules, in addition to providing a database of valid items for trial specific questions. Over two years of development have been necessary to finalize the development of the database and to store and classify over 400 items from all current EORTC modules and more than 5400 translations.

Results: Initial results of this Internet based instrument are positive. It has been used by EORTC members during the development process of new EORTC QL modules for High Dose Chemotherapy, Ophthalmic and Chronic Lymphocytic Leukemia. Initial feedback from module developers has been positive, and quality and speed have increased in the module development process. In addition, it has been used by EORTC members for selection of additional validated QL items to be used in EORTC Phase III clinical trials involving Gynecological and Genito-urinary patients.

Conclusion: Our initial results suggest that the approach on computerizing items from EORTC QL measures is successful, and has led to both improved use of QL items in our clinical trials, speeded up the process of selecting items for such trials and also speeded up the module development process. We plan to systematically evaluate the tools' use after one year of use within the EORTC. Presently, we are considering the possibility of linking real time data to QL items with a possibility of making the Item Bank a more functional research based tool.

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POSTER

Psychometric properties of fatigue measures with cancer patients - A review

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Purpose: Fatigue is one of the more common symptoms experienced by cancer patients, presenting a challenging and complex phenomenon for measurement. There is unclarity in the literature as to which measures should be used with cancer patients and just how valid such tools are. Researchers are asking questions about how fatigue is assessed? Why isn't there a gold standard measure? This paper examines fatigue tools used with cancer patients focusing on reliability and validity and reports on the outcome, proposing robust and valid tools to use with cancer patients.

Method: Between January and June 2000 a review of the literature was conducted on Medline (from 1980 to date) along with other databases (e.g. Cochrane Databases; UK N.H.S. C.R.D., UK N.I.C.; H.S.R. Databases; Cancerlit; SIGLE (to identify areas of grey literature) and OPAC 97 for the location of studies published in book format. In addition, published abstracts were reviewed and references of articles were checked. Only English language articles were selected.

Results: In total 11 measures were identified. Seven of these tools were solely fatigue measures, but four were QL measures with fatigue sub-scales. Seven measures were developed specifically for cancer patients, four were non-cancer specific but used with cancer patients. All the measures had multi-item scales, with the exception of one (Rhoten, 1982). Most scales were developed over the last five years, although one, (Pearson-Byars) was 50 years old. Many of the measures lacked cultural validity, with nine being developed in the USA, and two in Europe. Limited evidence existed for existing translations for use in the European setting, except with three measures. The majority of measures assessed fatigue as a multidimensional concept, although authors did not always agree on which concepts these were. In general, psychometric properties of reliability and validity were adequate.

Conclusion: It is clear that no gold standard fatigue tools are available for cancer patients. There is confusion over what are the key dimensions of fatigue tools, and measures identified to assess different aspects of fatigue. A major problem for the European setting is the lack of culturally valid fatigue measures. Two tools, the FACT-F and the EORTC QLQ-C30 fatigue sub-scale seem to offer reasonable methods to assessing fatigue in cancer patients. A more systematic review is presently being undertaken to further investigate this issue.

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POSTER

Pain after surgery for early-stage breast cancer (BC): incidence, characteristics and influence on quality of life (QL). Results from a retrospective study

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Introduction: Pain is a frequently unrecognized sequela of surgery for BC and may produce a relevant impact on patients QL. The different surgical options (radical mastectomy [RM], radical mastectomy with immediate breast reconstruction [RM+IBR], quadrantectomy plus radiotherapy [QUART]) may produce different outcomes in terms of pain incidence. The present report retrospectively assesses the incidence of pain in BC patients treated by different surgical techniques.

Material and method: We adopted a self-compilative questionnaire listing 129 items and incorporating the Italian version of the McGill Pain Questionnaire (MPQ). Furthermore, the items exploring the QL outcomes were grouped to obtain four subscales reflecting the physical well-being (PHY), the physical autonomy (POW), the psychological well-being (PSY) and the relational life (REL). Each of these subscales produced a standardized score ranging from 0 (worse) to 100 (best). The questionnaire was mailed to a consecutive series of 757 women who underwent RM or RM+IBR or QUART from 3/95 to 3/98.

Results: We analyzed 570 returned questionnaires (145 RM - 75 RM+IBR - 350 QUART). Two hundred eighteen patients (38%) declared pain as surgery consequence. This sequela usually begun within 3 months after treatment (47%), was localized more frequently in the axilla (59.6%) and/or on the scar (51.4%), was intermittent (69%), was not due to physical activities (57%) and rarely needed analgesics (10%). The pain was mainly described as aching (58%), tiring (40%) and tender (40%); the mean sensitivity and emotional scores on MPQ were 16.8 and 5.6 respectively. No statistically significant differences were observed among the different types of surgery in terms of pain occurrence and characteristics, except for a lower incidence of pain on the arm described in the QUART group.

The patients with pain had worse QL outcomes in comparison to the patients without (the results in terms of subscales scores are described in the table).

Subscales	Pain	No Pain	p value
PHY	57.5	70.3	< 0.0001
POW	77.6	84.9	< 0.001
PSY	64.5	79.6	< 0.0001
REL	56.9	69.7	< 0.0001

Conclusion: From our results, it seems that the different surgical techniques do not produce different incidence of pain. Nevertheless pain is a relevant sequela of BC surgery and is able to affect the patients QL.

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POSTER

Quality of life after axillary lymph node dissection versus sentinel lymph node biopsy

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Objective: Sentinel lymph node biopsy (SLN) is a less invasive method than axillary lymph node dissection (ALND) for axillary staging in breast cancer patients. The aim of this study is to determine the impact of pain on quality of life (QoL) and to assess the shoulder/arm mobility after the two surgical methods SLN and ALND.

Methods: 37 patients with newly diagnosed Stage I or II breast cancer were included in this prospective study. Group I (18 patients) received ALND, Group II (19 patients) received SLN. All patients completed the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 (QLQ-C30) and B24 (QLQ-B24), the McGill Pain Questionnaire (German version) and a visual analogue pain scale. Measurement of shoulder/arm mobility was performed in all patients. Evaluation was performed before surgery (baseline), 6 hours after surgery, on day 1, 3 and 5 after surgery, one week after demission and 3 months after surgery.

Results: Preoperative QoL was comparable in both groups. Pain was reported significantly more often in group I (81%) than in group II (16%). Shoulder/arm mobility was significantly better in group II (mean = 145.00) than in group I (mean = 114.58) for abduction (p 0.0002) and in group II (mean = 142.06) than in group I (mean = 121.25) for flexion (p 0.006).

Conclusion: Patients who receive SLN show less pain and better shoulder/arm mobility than patients after ALND. QoL is better in patients with SLN than in patients with ALND. Assessment of QoL should be considered in the establishment of new surgical methods.

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POSTER

Factors influencing cosmetic results after breast conserving management in breast cancer

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We aimed to determine predictive factors affecting cosmetic results after breast conserving management in breast cancer. Data on 96 patients with 97 breast cancer cases, who had been admitted to Uluda* University M. A. Radiotherapy Center between October 1995 and December 1998 and managed with breast conserving treatment, were analyzed to determine the factors affecting cosmetic outcome. Possible factors affecting cosmesis were grouped as patient related, tumor related and treatment related. Mann-Whitney-U test was used in univariate analyses while logistic regression was used in multivariate analyses. Median follow-up time was 29.5 months ranging between 11 and 53 months and median age at admission was 50 (range of 22-84). Cosmetic results were grouped in five categories, excellent, good, fair, poor and very poor, using criteria, such as presence of fibrosis, telangiectasia, shape of breast, asymmetry, status of areola, pigmentation. Treated breasts were scored by the patients, three radiation oncologists and a breast surgeon independently. In the analy-

sis performed using scores given by the patients, cases with scores 3 and above (unsatisfactory) were compared with cases with scores below 3 (satisfactory). Eighty-two patients (84%) considered cosmetic result as satisfactory (excellent/good) while 15 patients (16%) considered unsatisfactory (fair/poor/very poor). In univariate analysis using Mann-Whitney-U test, type of surgery (p=0.0655) was the statistically significant factors affecting cosmetic results. In multivariate analysis using logistic regression, tumor quadrant (p=0.0060) and elapsed radiation therapy days (p=0.0090) were the most significant factors. Median values were taken into consideration for the scores given by the physicians and cases with scores 3 and above (unsatisfactory) were compared with cases with scores below 3 (satisfactory). Eighty-two cases were evaluated as satisfactory (84%) while 15 cases were unsatisfactory (16%). In this set of data, patient age (p=0.0144), menopausal status (p=0.0111), institution where surgery was performed (p=0.0045), type of surgery (p=0.0044), placement of metallic clips (p=0.0083) and skin fibrosis (p=0.038) were found to be significant in univariate analysis using Mann-Whitney-U test. In multivariate analysis using logistic regression, institution where surgery took place (p=0.0015), menopausal status (p=0.0087) and telangiectasia (p=0.0657) were the most significant factors.

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POSTER

Epoetin alfa overcomes much of the QOL deficit seen in anaemic cancer patients

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Background: Anaemia has been shown to have a marked effect on Quality-of-life (QOL) in cancer patients. Comparison of clinical trial QOL data with population norm data shows how large an impact treatment of anaemia can have.

Methods: The FACT-An (Functional Assessment of Cancer Therapy-Anaemia) QOL instrument was administered to a nationally representative sample of 1400 people using an Internet survey panel in the US. These results were then compared to FACT-An results from a 375-patient, randomized, double-blind, clinical trial evaluating epoetin alfa vs. standard care in anaemic cancer patients.

Results: 1080 people responded to the Internet survey. On a 0-100 scale (with higher scores indicating better QOL) mean QOL scores were 74.2 for General QOL, 77.06 for Fatigue, and 77.6 for the Anaemia subscale. In the clinical trial, prior to starting treatment, baseline scores for the Epoetin alfa group were 68.4 (General QOL), 57.1 (Fatigue) and 60.5 (Anaemia subscale), a deficit of 5.8, 19.96, and 17.1, respectively, from the norms. Baseline scores for the control group were similar. By the end of the clinical trial, epoetin alfa resulted in a statistically significant improvement in QOL over standard care of 5.61 (General QOL), 9.90 (Fatigue), and 15.89 (Anaemia subscale). This advantage represents 97%, 50%, and 93%, respectively, of the initial QOL deficits. Nearly the entire deficits for General QOL and the Anaemia subscale are completely corrected, while the deficit in Fatigue is cut in half.

Conclusion: Based on norm data for the FACT-An, epoetin alfa leads to large and significant improvements in QOL, relative to the initial QOL deficit. We interpret these changes as highly significant and favourable for anaemic cancer patients.

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POSTER

Psychometric properties of the EORTC quality of life core questionnaire (QLQ-C30) in EORTC trials

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Purpose: The EORTC QLQ-C30 is one of the most widely used QL measures applied in cancer clinical trials. This study aimed to look at the