Original Articles

Validation of EORTC quality-of-life questionnaire in Indian women with operable breast cancer

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ABSTRACT

Background. The European Organization for Research and Treatment of Cancer (EORTC) module QLQ-C30 and the breast cancer-specific module BR-23 have been validated worldwide to assess the quality of life (QOL) in women with breast cancer. No such study has been published on Indian women using EORTC questionnaires.

Methods. QOL was assessed in relation to surgery, adjuvant chemotherapy, radiation therapy and hormone therapy in 299 Indian women with operable breast cancer (OBC) at the Breast Unit of Tata Memorial Hospital (TMH), Mumbai, from October 1998 to September 2001. The QLQ-C30 module was used to assess physical health, emotional, cognitive and social functioning, and the BR-23 module to assess breast cancer treatment-related symptoms. Assessment was done at 3 visits: visit 1 (after surgery); visit 2 (during adjuvant therapy) and visit 3 (on completion of adjuvant therapy).

Results. Of the 299 women at first visit, 274 (91.6%) completed the visit 2 questionnaire and 239 (80%) completed the visit 3 questionnaire. Only those women who filled the questionnaires at all 3 visits were included as 'valid visits' for analysis (193 of 299; 64.5%). The reliability and validity of the English and translated versions of the questionnaires were tested by Cronbach alpha (0.61–0.96) and item–scale correlation (0.63–0.93). Women with breast conservation treatment had a superior body image as compared to those with mastectomy ($p < 0.001$). Physical, emotional and cognitive functions were not related to the type of surgery. Global QOL, physical, sexual and role functioning were found to deteriorate with chemotherapy ($p \leq 0.01$). Radiotherapy had only local adverse effects ($p < 0.001$), while hormone therapy had no adverse impact on QOL.

Conclusion. QLQ-C30 and BR-23 questionnaires can be used reliably to assess QOL in Indian patients. The translated versions were found to be valid for further use in clinical trials on Indian women with breast cancer.

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INTRODUCTION

Advances in adjuvant therapy for breast cancer have shown modest gains varying from 1% to 9%. As the magnitude of benefit decreases, side-effects and quality-adjusted benefits gain importance. It is important to note that following a relapse, the response to therapy and improvement in time to progression of disease are in increments of a few months, and quality-of-life (QOL) issues are more important in these patients.

In India, the incidence of breast cancer has steadily increased over the years with 100 000 new cases being diagnosed every year.[1] At a given time, there are as many as 1 million patients with breast cancer in India. The lifetime risk of developing breast cancer is 1:30 (incidence rate: 20/100 000) in urban India and 1:65 (incidence rate: 8.6/100 000) in rural India as compared to 1 in 8 in the USA. At the Tata Memorial Hospital (TMH), Mumbai, a tertiary cancer referral centre in India, about 60% of women present with early breast cancer, 35% with locally advanced disease and 5% have metastases at presentation.

Cultural and ethnic influences have a major impact on the treatment measures and outcomes between western and Indian women. The European Organization for Research and Treatment of Cancer (EORTC) module QLQ-C30[2,3] and the breast cancer-specific module BR-23[4] have been validated to assess QOL in western women with breast cancer. These questionnaires were designed keeping in mind the lifestyle of western women. The reliability and validity of the questionnaire has thereafter been tested and found to be highly consistent across different language and cultural groups in English-speaking countries, and northern and southern Europe.[2] Whether these modules are equally reliable in Indian languages and in our cultural milieu has not been studied. The functional assessment of cancer therapy for breast cancer (FACT-B) has been reported in some Indian women.[5]

The standard treatment of primary operable breast cancer (OBC) includes a combination of surgery, radiotherapy, chemotherapy and/or hormone therapy. Large randomized trials[6] have shown that breast conservation treatment (BCT) and modified radical mastectomy (MRM) for early breast cancer are comparable with respect to the risk of local recurrence and overall survival. As regards QOL, BCT and mastectomy have been shown to have different impacts.[7–9] While some studies have shown that

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compared with mastectomy, BCT resulted in a better overall QOL,[10–13] other studies have shown equivocal[7] or even worse[14] results.

QOL assessment is an important surrogate end-point in various clinical trials testing a treatment intervention, in addition to the actuarial improvement in disease-free survival or overall survival. While a proportional reduction in the odds of recurrence or death is observed irrespective of nodal status,[15] the absolute benefit from systemic therapy is clearly more among those with a higher risk of recurrence.[16] Adjuvant radiotherapy is indicated in all high-risk women with tumours >5 cm in size or with metastasis in >3 nodes in the axilla.[17,18] In such situations the use of adjuvant chemo-radiation is also indicated, irrespective of the impact on QOL. The controversies arise in cases that have a low risk of recurrence and derive a minimal absolute degree of benefit from adjuvant treatment in the presence of considerable co-morbid medical conditions or in elderly patients. The effects on QOL can also be the primary end-point in certain studies comparing two nearly similar treatment modalities. We translated the QLQ-C30 and BR-23 modules into three local languages and administered these to ascertain their validity, and to assess the QOL following surgery and adjuvant therapy in Indian women with early OBC.

METHODS

Questionnaire

The EORTC module QLQ-C30 is a 30-item questionnaire composed of 5 multi-item functional subscales: physical health, role function, emotional function, cognitive function and social functioning; 3 multi-item symptom scales measuring fatigue, pain and emesis; a global health subscale and 6 single items to assess financial impact and general symptoms.

The BR-23 module evaluates treatment-related symptoms of breast cancer. It incorporates 3 functional scales (body image, future perspectives and sexuality) and 4 symptom scales (arm symptoms, breast symptoms, hair loss and side-effects of systemic therapy).

Translation methodology

The EORTC office and the clinical research secretariat cell at TMH coordinated translation of the questionnaire. There were two rounds of back and forth translation for the purpose of validation. The translations were done in three Indian languages—Gujarati, Marathi and Hindi.

Patients

Women with OBC undergoing primary surgery in the Breast Unit at TMH from October 1998 to September 2001 were included. Adjuvant systemic therapy and radiotherapy were administered postoperatively based on the histopathological report of the patients. None of the women had received neoadjuvant chemotherapy or hormone therapy.

The QOL during treatment was objectively assessed with the EORTC modules QLQ-C30 and BR-23 in English and the translated versions. A minimal level of education was required for the patient to be able to read, comprehend and complete the questionnaires on her own.

Management protocol

Women with OBC were treated by a standard protocol in the Breast Unit, wherein after confirmation of the diagnosis of breast cancer by fine-needle aspiration cytology (FNAC) or core biopsy, they underwent BCT or MRM based on the feasibility of conserving the breast, patients' choice and compliance with radiotherapy. On an average, the sutures were removed 12–14 days after surgery by which time the histopathological report was also available and adjuvant therapy was planned.

All women with a tumour size $\geq$1 cm and/or lymph node metastasis received adjuvant systemic therapy and were counselled by the breast care nurse. Adjuvant chemotherapy (cyclophosphamide, methotrexate and 5-fluorouracil [CMF] or cyclophosphamide, doxorubicin and 5-fluorouracil [CAF]) was administered in 6 cycles at 3-weekly intervals. The chemotherapy schedule lasted 6 months with CMF and 4.5 months with anthracycline-based chemotherapy. Adjuvant radiotherapy was administered concurrently with CMF chemotherapy and sequentially after CAF chemotherapy. As per the unit protocol, all women who underwent BCT received postoperative radiotherapy and, after mastectomy, the chest wall was irradiated if the tumour was $\geq$5 cm in size or if >3 axillary nodes were positive for metastasis. Sequential radiotherapy was started approximately 2 weeks after completing CAF chemotherapy and was usually completed in 6–7 weeks. The adjuvant treatment lasted 8.5$\pm$1 months. All women who had endocrine-responsive tumours received tamoxifen 20 mg once daily or 10 mg twice daily for 5 years. After completing adjuvant chemotherapy, the patient was reviewed every 6 months.

Data collection

The QLQ-C30 and BR-23 modules were administered at three time-points. The questionnaire was served for the first time (visit 1) within 2–4 weeks of surgery. The questionnaire was served the second time (visit 2) when the patient was on adjuvant therapy (chemotherapy, hormone therapy and/or radiotherapy), 2–8 months after surgery (average 4.08 months); and the third time (visit 3) it was served after the completion of adjuvant chemotherapy, 6–18 months after the surgery (average 9.01 months). The breast care nurse served the questionnaire but the patient herself, unassisted by the nurse or any other individual, completed the questionnaire. Thus, only those women who could comprehend the questions asked were included in the study. Only those women who completed the QOL questionnaire on all the 3 visits were included in the final analysis.

Statistical analysis

Scoring of the QLQ-C30 and BR-23 was done according to the scoring procedures described in the EORTC scoring manuals. A range of analyses was conducted to establish scale reliability and to evaluate the validity of the questionnaire. Reliability or internal consistency of the multi-item questionnaire scales for the entire sample was assessed by Cronbach alpha coefficient. A magnitude of $\geq$0.70 was sought. Multitrait scaling analysis was used to examine the extent to which the items of the questionnaire could be combined into a hypothesized multi-item scale by item–scale correlation. If the item–scale correlation coefficient was $\geq$0.40, item convergent validity was considered acceptable.

Statistical methodology

The type of surgery performed (MRM or BCT) and whether adjuvant chemotherapy, radiotherapy or hormone therapy was given or not, were used to divide the patients into subgroups as we expected health-related QOL to differ among the groups.

Non-parametric tests were used because of non-normal distribution of scores. The Mann–Whitney U test was used to compare

scores between the two groups at each visit and the Friedman test to test for changes over time.

The global QOL score (q29, q30 in QLQ-C30) has a normal distribution. Analysis of variance for repeated measures was used for comparing global QOL scores between types of surgery and adjuvant therapy.

RESULTS

Two hundred and ninety-nine women were included in the study. Of these, 274 (91.6%) completed the questionnaire on visit 2 and 239 (80%) on visit 3. One hundred and ninety-three women (64.5%) completed all the three visits within the specified time periods and were included in the final analysis as valid visits; 60 forms were completed in English and 133 in the translated local language version. The mean age of the women was 44.2 years (range 24–72 years); 67% of women were premenopausal and 33% postmenopausal (Table I).

TABLE I. Demographic profile of patients included in QOL study (*n*=193)

Parameter	*n*	(%)
Occupation		
Housewife	135	(69.9)
Service	51	(26.4)
Professional/Others	7	(3.7)
Education		
Primary	101	(52.3)
Secondary	31	(16.1)
Graduation	42	(21.8)
Postgraduation	19	(9.8)
Marital status		
Unmarried	8	(4.1)
Married	174	(90.2)
Divorcee/Widow	11	(5.7)
Menopausal status		
Premenopausal	129	(66.9)
Postmenopausal	64	(33.1)
Type of surgery		
Modified radical mastectomy	77	(39.9)
Breast conservation treatment	116	(60.1)
Histology		
Infiltrating duct carcinoma	173	(89.7)
Others	20	(10.3)

TABLE II. Reliability and validity of the EORTC questionnaire by Cronbach alpha (*n*=193)

Internal consistency (Cronbach alpha) of the QLQ-C30 scales

Visit	Functioning					Fatigue	Pain	Nausea/ vomiting	QOL
	P	R	E	C	S				
1	0.64	0.78	0.85	0.49	0.76	0.76	0.66	0.57	0.86
2	0.75	0.76	0.86	0.46	0.81	0.76	0.70	0.66	0.91
3	0.75	0.81	0.90	0.62	0.76	0.84	0.76	0.74	0.96

Internal consistency (Cronbach alpha) of the QLQ–BR23 scales

Visit	Body image	Sexual functioning	Symptoms		Side-effects of systemic therapy
			Arm	Breast	
1	0.81	0.81	0.73	0.66	0.61
2	0.84	0.83	0.70	0.77	0.80
3	0.86	0.91	0.75	0.59	0.59

P Physical R Role E Emotional C Cognitive S Social

The tumours were reported as infiltrating duct carcinoma in 89.7% of cases, ranging from 0.1 to 7.0 cm with a mean tumour size of 3.25 cm. The tumours were positive for oestrogen receptors in 26% of cases and progesterone receptors in 41%. BCT was done in 60.1% of women. Based on the treatment protocol and eligibility criteria, 90% of women received adjuvant chemotherapy, 51% hormone therapy and 75% radiotherapy.

Cronbach alpha (Table II) and individual item–scale correlation tested the validity and reliability of the QLQ-C30 and BR-23 questionnaires. The reliability of the questionnaire results was confirmed, as a value of nearly 0.70 or greater was obtained for all domains except cognitive function.

The translated versions were validated by Cronbach alpha and the scores between the English version and translated versions were compared at visit 1 (Table III). There was no statistically significant difference.

The effect of surgery on QOL was assessed linearly with time, i.e. between visit 1 and visit 3 using Friedman test, and also between types of surgery performed (BCT *v.* mastectomy) using the Mann–Whitney U test. The global QOL scale, functional scales and symptom scales showed no significant change from visits 1 to 3 between BCT and mastectomy. Women who underwent BCT maintained a better body image through visit 1 ($p<0.001$) and visit 2 ($p=0.055$) compared with women who underwent mastectomy. The differences disappeared by visit 3 (average 9 months after surgery). Women who had BCT had significantly more local symptoms than after mastectomy in visits 2 and 3 ($p<0.01$). This corresponded with the period of adjuvant radiotherapy (Table IV).

Chemotherapy significantly affected the global QOL with poor scores during treatment ($p=0.016$). The results also showed lower functional scales especially with respect to sexual function ($p=0.02$) after chemotherapy. Women receiving chemotherapy experienced severe nausea and vomiting ($p<0.001$), were upset over hair loss ($p<0.001$), and had more arm symptoms ($p<0.01$) and systemic effects ($p<0.001$; Table V).

Adjuvant radiotherapy resulted in deterioration in social functions ($p=0.02$) during treatment, with significantly more breast symptoms ($p<0.001$) as compared with women not receiving adjuvant radiotherapy (Table VI). Hormone therapy had no significant effect on the QOL as assessed by both questionnaires.

DISCUSSION

The EORTC developed the 30-item QOL questionnaire (QLQ-C30) as a self-supporting, cancer-specific measure of health-

TABLE III. Comparison of Cronbach alpha score between the English version and translated Indian language versions of EORTC QLQ-C30 and BR-23

Item scales	English	Translated versions
Functioning		
Physical	0.617	0.656
Role	0.827	0.738
Emotional	0.831	0.831
Cognitive	0.233	0.437
Social	0.784	0.787
Quality-of-life	0.803	0.832
Systemic side-effects	0.641	0.707
Body image	0.782	0.814
Sexual functioning	0.883	0.744
Arm symptoms	0.654	0.735
Breast symptoms	0.716	0.647

TABLE IV. Comparative QOL assessments between visits 1 and 3 by the Friedman test, and within each visit between breast conservation treatment (BCT) and modified radical mastectomy (MRM) by Mann–Whitney U test

Item scale	Therapy	Visit 1	Visit 2	Visit 3	p value*
Functioning					
Physical	MRM	77.14 (16.2)	76.10 (16.9)	76.71 (18.4)	0.95
	BCT	80.86 (12.5)	74.19 (17.8)	78.41 (16.5)	0.002
	p value†	0.14	0.41	0.63	
Role	MRM	75.76 (27.1)	76.84 (26.6)	80.30 (24.4)	0.211
	BCT	74.85 (27.4)	76.87 (23.4)	84.34 (22.9)	0.001
	p value†	0.79	0.69	0.18	
Emotional	MRM	69.08 (23.6)	67.98 (27.2)	71.05 (27.5)	0.42
	BCT	69.60 (24.2)	71.09 (24.4)	70.51 (24.7)	0.001
	p value†	0.63	0.57	0.76	
Social	MRM	74.78 (28.1)	72.37 (28.7)	74.56 (28.2)	0.58
	BCT	77.39 (28.9)	75.79 (28.5)	81.73 (23.4)	0.04
	p value†	0.52	0.38	0.12	
Cognitive	MRM	85.75 (21.6)	78.20 (23.3)	82.24 (20.9)	0.004
	BCT	88.55 (17.2)	84.34 (19.7)	81.01 (21.9)	0.001
	p value†	0.46	0.08	0.75	
Body	MRM	73.05 (23.9)	72.94 (26.5)	71.43 (31.1)	0.83
image	BCT	88.48 (17.3)	80.58 (22.7)	82.80 (21.1)	<0.001
	p value†	<0.001	0.055	0.47	
Symptoms					
Arm	MRM	37.33 (22.9)	26.22 (22.8)	30.52 (25.1)	<0.001
	BCT	32.75 (21.1)	29.19 (21.5)	27.34 (20.7)	0.013
	p value†	0.29	0.17	0.64	
Breast	MRM	18.46 (16.3)	15.30 (16.6)	16.51 (18.5)	0.57
	BCT	19.73 (17.7)	28.19 (21.9)	22.92 (18.6)	0.005
	p value†	0.67	<0.0001	0.003	
Systemic	MRM	16.08 (13.6)	32.89 (19.7)	28.14 (20.9)	<0.001
therapy	BCT	13.83 (11.6)	34.91 (20.3)	27.77 (19.5)	<0.001
side-effects	p value†	0.47	0.59	0.95	
Sexual	MRM	81.34 (23.3)	74.88 (27.1)	72.88 (26.7)	
functioning	BCT	79.57 (23.1)	75.16 (23.8)	73.04 (25.4)	0.036
	p value†	0.69	0.79	0.89	

* Friedman test † Mann–Whitney U test
Figures in parentheses indicate ± standard deviation

related QOL. The QLQ-C30 was intended to be applicable across a wide range of cancer diagnoses and treatments. Its main purpose was to obtain information about the impact of disease and treatment on the daily living of patients with cancer. One of the largest validation studies for QLQ-C30 was reported by McLachlan *et al.*[3] in 150 Canadian women with metastatic breast cancer. The findings supported the use of QLQ-C30 subscales for assessing global health, role function, social function and emotional function. The module BR-23 was added later[4] as a breast cancer-specific questionnaire to supplement the core instrument and thus be highly relevant for assessing the QOL of patients with breast cancer participating in clinical trials.

The reliability and validity of the EORTC instrument has been tested not only in western women but also in women from the east (Korea) and those from a different religious following (Turkish). In the Korean study, in a known-group comparison, there were marked group differences between patients differing in the stage of disease. The performance on the Korean version of the EORTC QLQ-BR23 questionnaire was in the expected direction for almost all functioning and symptom scores, and compared well between normal individuals and patients with breast cancer.[19] The Turkish study was carried out in 202 patients with lung cancer and tested

TABLE V. QOL assessment between visits 1 and 3 by the Friedman test, and within each visit between those receiving and not receiving chemotherapy by Mann–Whitney U test

Item scale	Therapy	Visit 1	Visit 2	Visit 3	p value*
Functioning					
Physical	Yes	79.84 (13.5)	74.64 (17.7)	77.37 (17.4)	0.01
	No	75.09 (19.4)	77.89 (14.8)	81.05 (16.5)	0.14
	p value†	0.37	0.55	0.34	
Role	Yes	74.62 (27.1)	76.15 (24.1)	81.99 (23.6)	0.001
	No	80.70 (28.5)	83.33 (29.4)	89.47 (22.4)	0.10
	p value†	0.21	0.06	0.72	
Cognitive	Yes	87.19 (19.1)	81.69 (21.4)	80.92 (21.6)	<0.001
	No	89.81 (18.2)	84.26 (20.9)	87.04 (20.3)	0.72
	p value†	0.52	0.56	0.25	
Body	Yes	81.98 (21.5)	77.22 (24.2)	77.78 (25.6)	0.012
image	No	85.09 (22.2)	80.26 (27.7)	82.46 (30.2)	0.38
	p value†	0.33	0.27	0.72	
Symptoms					
Arm	Yes	34.63 (21.9)	28.75 (21.6)	29.53 (22.0)	<0.001
	No	33.95 (22.1)	20.99 (26.1)	19.75 (26.0)	0.003
	p value†	0.72	0.03	0.009	
Systemic	Yes	15.21 (12.7)	36.33 (19.3)	29.6 (19.3)	<0.001
therapy	No	10.27 (8.3)	13.78 (14.6)	12.32 (20.6)	0.63
side-effects	p value†	0.12	<0.001	<0.001	
Sexual	Yes	79.76 (23.7)	75.11 (25.5)	72.84 (26.3)	0.006
functioning	No	85.56 (15.3)	74.44 (20.1)	74.44 (20.8)	0.09
	p value†	0.59	0.99	0.66	

* Friedman test † Mann–Whitney U test
Figures in parentheses indicate ± standard deviation

TABLE VI. Adjuvant radiotherapy and quality-of-life

Item scale	Therapy	Visit 1	Visit 2	Visit 3	p value*
Functioning					
Physical	Yes	80.42 (13.6)	73.84 (18.2)	77.52 (16.9)	0.001
	No	76.33 (15.5)	78.23 (14.6)	78.37 (18.4)	0.15
	p value†	0.66	0.17	0.55	
Role	Yes	75.58 (26.4)	76.39 (28.0)	83.45 (28.5)	0.001
	No	74.15 (29.7)	78.23 (26.8)	80.61 (23.6)	0.343
	p value†	0.91	0.396	0.28	
Social	Yes	76.29 (28.4)	73.94 (28.7)	80.16 (24.2)	0.02
	No	76.53 (29.6)	75.85 (28.5)	75.17 (29.1)	0.97
	p value†	0.81	0.60	0.37	
Cognitive	Yes	87.09 (19.9)	82.28 (21.2)	81.69 (22.1)	0.001
	No	88.44 (16.0)	80.95 (21.8)	80.95 (19.3)	0.06
	p value†	0.93	0.82	0.63	
Body	Yes	84.73 (20.9)	77.97 (23.8)	78.65 (25.6)	<0.001
image	No	75.17 (22.1)	76.19 (26.8)	77.04 (27.8)	0.29
	p value†	0.003	0.93	0.84	
Symptoms					
Arm	Yes	34.20 (22.1)	29.75 (22.2)	29.83 (22.8)	0.009
	No	35.65 (21.6)	22.92 (20.9)	25.00 (21.6)	<0.001
	p value†	0.77	0.27	0.214	
Breast	Yes	19.87 (17.6)	26.94 (21.3)	23.39 (19.7)	0.014
	No	17.27 (15.8)	11.59 (11.0)	11.29 (11.9)	0.29
	p value†	0.50	<0.001	<0.001	
Systemic	Yes	15.00 (12.9)	35.68 (20.7)	28.85 (20.4)	<0.001
therapy	No	13.89 (10.9)	29.62 (17.4)	28.17 (18.6)	<0.001
side-effects	p value†	0.72	0.14	0.39	
Sexual	Yes	78.84 (23.1)	75.26 (28.1)	73.94 (24.1)	0.07
functioning	No	84.49 (22.8)	74.42 (25.3)	70.16 (30.6)	0.002
	p value†	0.17	0.98	0.89	

* Friedman test †Mann–Whitney U test
Figures in parentheses indicate ± standard deviation

the validity of the Turkish version of the EORTC QLQ-C30 v. 2.0. All subscales met the minimal standards of reliability. Global QOL was substantially correlated with most of the scales except cognitive functioning.[20]

Our study on Indian women with breast cancer confirmed the reliability and validity of the EORTC QLQ-C30 in assessing the overall QOL of Indian women with breast cancer. The BR-23 was also validated in the current study, as the breast symptoms, body image and systemic therapy side-effects scales were clearly responsive to treatment-induced changes.

The validity and reliability of the translated versions of the QOL questionnaire were tested by comparison between the English version group and the local language version groups. The similarity of Cronbach alpha values obtained validates the local language version for use among Indian women. The validation was further consolidated by the observations made with respect to QOL assessment during treatment of breast cancer.

Our study showed no difference in any aspect of overall QOL between BCT and MRM except body image, which was significantly better after BCT and breast symptoms which worsened during and after radiotherapy in the BCT group. The differences, however, disappeared by visit 3 (average 9 months after surgery) indicating a late coping capability and adjustment with self-image in women after MRM. A study by Kiebert *et al*.[8] supports the findings of our study. They reviewed 18 studies investigating the impact of BCT *v*. MRM on QOL with respect to treatment modality, stage of disease, methodological issues and end-results (psychological discomfort, change in pattern of life, and fears and concerns). Only a better body image and sexual functioning favoured the use of BCT.

The impact of BCT and MRM on QOL has shown contradictory results in different studies. A comparative study in Munich[12] in 152 pair-matched patients evaluated the QOL in women initially treated for stages I–III breast cancer without evidence of distant metastasis. In this study, the QOL questionnaire was answered after a median interval of 46 months following primary treatment. No difference was observed between the two groups in terms of all QOL items as measured by the QLQ-C30. However, certain additional questions revealed that women in the mastectomy group were less satisfied with the cosmetic result of their primary operation ($p<0.0001$), were more likely to feel the basic changes in their appearance ($p<0.0001$) and were more likely to be emotionally stressed by these facts ($p<0.0001$). In contrast, Cohen *et al*.[14] found that women who had BCT experienced significantly greater levels of psychological distress and marginally worse QOL 40 months after surgery than women who underwent MRM. Both these studies have looked at the late effects of BCT *v*. MRM on the QOL. The early effect on QOL has been assessed mainly in relation to radiation therapy after BCT. In a randomized trial setting, the Ontario Clinical Oncology Group[21] studied serial QOL in two groups of women with lymph node-negative breast cancer who underwent BCT; radiotherapy following BCT and those who did not. Breast irradiation resulted in increased breast symptoms compared with controls during and after the treatment, which disappeared by 2 years post treatment.

Adjuvant systemic therapy for early breast cancer is effective but is known to be associated with significant side-effects. In our study too, chemotherapy resulted in significant symptoms such as nausea and vomiting ($p<0.001$). Also, patients were most upset over hair loss and had more arm symptoms after chemotherapy ($p<0.001$).

Adjuvant radiotherapy resulted in mainly local symptoms in the arm ($p=0.009$) and breast ($p<0.001$), which were also associated with deterioration in social function ($p<0.021$). The impact on other function scales was not significant. There were no systemic effects of radiotherapy.

Adjuvant hormone therapy had no effect on QOL during treatment. Vaginal dryness was experienced by most women due to increased vaginal epithelial proliferation but did not significantly affect their sexual life.

Conclusion

The EORTC questionnaires QLQ-C30 and BR-23 are applicable to Indian women in spite of major language and cultural differences from western society. The QOL scores of the translated versions were similar to the original English version and, therefore, can be used to assess the QOL of Indian women. The statistical analysis of a QOL questionnaire is itself a process in evolution. It has many shortcomings, multiple comparisons, objective conversion of a subjective feeling, etc. These need to be considered before any conclusions are drawn from a QOL analysis.

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