

An international Phase 4 field study to analyse the psychometric properties of the updated module on assessing quality of life of patients with breast cancer

EORTC QLQ BR45

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Background

Females breast cancer is still the most frequent type of cancer in Europe with 21 per 100,000 women. The EORTC QLQ-BR23 was one of the first modules developed to be used in conjunction with the core questionnaire EORTC QLQ-C30 and was published in 1996. Since the beginning of the work on the EORTC QLQ-BR23 some 20 years ago, much knowledge has been gathered about the epidemiology of breast cancer, and major advances have been made with regard to diagnostic and therapeutic options. Therefore, the EORTC QLG decided to update the BR23. A phase 1 to 3 module development project has been completed. This resulted in a 45 item module, retaining 23 of the original items and adding 22 new items, particularly tapping into the side effects of new systemic and local therapies.

Aim

The aim of the Phase 4 study is to test the psychometric properties (scale structure, reliability, responsiveness to change, and validity) of the EORTC QLQ-BR45 in conjunction with the EORTC QLQ-C30 in patients diagnosed with breast cancer. Participants will be enrolled in different groups according to their disease stage (localized & locally advanced, metastatic, follow up [FU]). Various combinations of therapies are permissible resulting in different subgroups. According to sample size calculations, we will include a total of N = 500 patients from at least 12 countries.

Method

Participants will be invited to complete the QLQ-C30 and the QLQ-BR45, followed by the Debriefing Questionnaire. Data of all patients will be used to evaluate the scale structure, internal consistency, convergent and discriminant validity. A subgroup of patients with no evidence of disease (no change in health status; follow up with or without Antihormonal Therapy [AHT]) will be invited to complete the QLQ-C30 and the QLQ-BR45 for a second time a week later for the test-retest analysis. Patients who change the disease or treatment status after the first assessment will be invited to complete a second set of questionnaires for the response to change analysis. Sociodemographic and clinical data will be recorded using standardized case report forms (CRF). Inclusion Criteria: histologically confirmed diagnosis of breast cancer, no previous primary or recurrent tumour, ability to understand the language of the questionnaire, mental fitness to complete a questionnaire, 18 years of age or above, written informed consent.

EORTC QLQ-BR45

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	Not at All	A Little	Quite a Bit	Very Much
31. Have you had a dry mouth?	1	2	3	4
32. Have food and drink tasted different than usual?	1	2	3	4
33. Have your eyes been painful, irritated or watery?	1	2	3	4
34. Have you lost any hair?	1	2	3	4
35. Answer this question only if you have lost any hair: Have you been upset by the loss of your hair?	1	2	3	4
36. Have you felt ill or unwell?	1	2	3	4
37. Have you had hot flashes?	1	2	3	4
38. Have you had headaches?	1	2	3	4
39. Have you felt physically less attractive as a result of your disease or treatment?	1	2	3	4
40. Have you felt less feminine as a result of your disease or treatment?	1	2	3	4
41. Have you had problems looking at yourself naked?	1	2	3	4
42. Have you been dissatisfied with your body?	1	2	3	4
43. Have you worried about your health in the future?	1	2	3	4
During the past four weeks:	Not at All	A Little	Quite a Bit	Very Much
44. Have you been interested in sex?	1	2	3	4
45. Have you been sexually active (with or without intercourse)?	1	2	3	4
46. Has sex been enjoyable for you?	1	2	3	4
During the past week:	Not at All	A Little	Quite a Bit	Very Much
47. Have you had any pain in your arm or shoulder?	1	2	3	4
48. Have you had a swollen arm or hand?	1	2	3	4
49. Have you had problems raising your arm or moving it sideways?	1	2	3	4
50. Have you had any pain in the area of your affected breast?	1	2	3	4
51. Has the area of your affected breast been swollen?	1	2	3	4
52. Has the area of your affected breast been over-sensitive?	1	2	3	4
53. Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?	1	2	3	4
54. Have you sweated excessively?	1	2	3	4
55. Have you had mood swings?	1	2	3	4
56. Have you been dizzy?	1	2	3	4
57. Have you had soreness in your mouth?	1	2	3	4
58. Have you had any redness in your mouth?	1	2	3	4
59. Have you had pain in your hands or feet?	1	2	3	4
60. Have you had any redness on your hands or feet?	1	2	3	4
61. Have you had tingling in your fingers or toes?	1	2	3	4
62. Have you had numbness in your fingers or toes?	1	2	3	4
63. Have you had problems with your joints?	1	2	3	4
64. Have you had stiffness in your joints?	1	2	3	4
65. Have you had pain in your joints?	1	2	3	4
66. Have you had aches or pains in your bones?	1	2	3	4
67. Have you had aches or pains in your muscles?	1	2	3	4
68. Have you gained weight?	1	2	3	4
69. Has weight gain been a problem for you?	1	2	3	4
During the past four weeks:	Not at All	A Little	Quite a Bit	Very Much
70. Have you had a dry vagina?	1	2	3	4
71. Have you had discomfort in your vagina?	1	2	3	4
Please answer the following two questions only if you have been sexually active:				
72. Have you had pain in your vagina during sexual activity?	1	2	3	4
73. Have you experienced a dry vagina during sexual activity?	1	2	3	4
During the past week:	Not at All	A Little	Quite a Bit	Very Much
74. Have you been satisfied with the cosmetic result of the surgery?	1	2	3	4
75. Have you been satisfied with the appearance of the skin of your affected breast (thoracic area)?	1	2	3	4

Figure 1. EORTC BR 45. The questionnaire module to be validated. The module begins with number 31 because it will always be completed together with the EORTC C30 core questionnaire. New items in blue.

Current State (December 2020)

The Phase 4 of patient recruitment and data collection (until June 2021) is ongoing. 20 centres from 16 countries and 14 languages are participating. Currently we have the data of N = 325 patients. The data collection will continue until June 2021. The following steps are the data analysis, the preparation of a report and the production of the final questionnaire.

Patient Sample

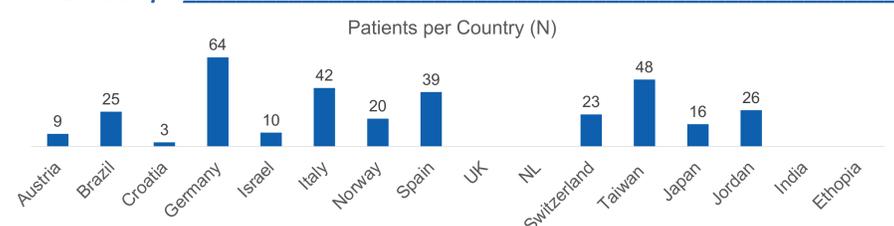


Figure 2. Number (N) of patients recruited per country until December 2020.

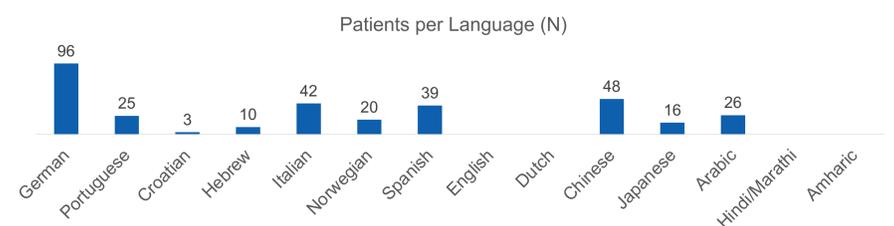


Figure 3. Number (N) of patients recruited per language until December 2020.

Table 1. Sociodemographic patient data

Age (M= 55.2, Min = 28, Max = 90, SD = 11.28)	N	Percent
20 - 29	2	0,6%
30 - 39	22	6,8%
40 - 49	78	24,0%
50 - 59	113	34,8%
60 - 69	73	22,5%
70 - 79	29	8,9%
80 - 89	5	1,5%
Livingsituation		
alone	56	17,2%
with partner or family	263	80,9%
unknown	5	1,5%
Educationlevel		
less than compulsory	16	4,9%
compulsory	78	24,0%
post compulsory, below university	117	36,0%
university level or above	112	34,5%
missing	2	0,6%
Employment		
fulltime	111	34,2%
part time	67	20,6%
homemaker	56	17,2%
training/education	4	1,2%
retired	65	20,0%
other	20	6,2%
missing	2	0,6%
Sexually active		
yes	149	45,8%
no	164	50,5%
missing	12	3,7%
Menopausal Status		
pre-menopausal	66	20,3%
post-menopausal	177	54,5%
treatment related menopause	59	18,2%
unknown	22	9,9,7%
Years since diagnosis		
less than 5 years	275	84,6%
5 to 10 years	33	10,2%
more than 10 years	15	4,6%

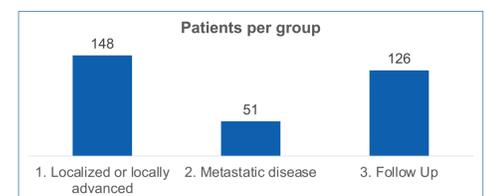


Figure 4. Number (N) of patients in different groups according to their disease stage.

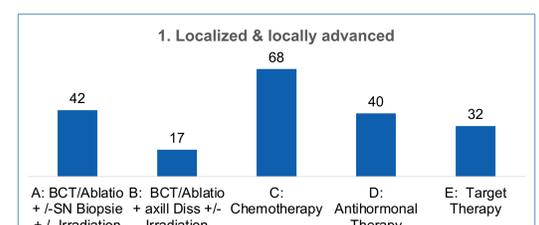


Figure 5. Localized & locally advanced disease. Number (N) of patients per subgroup. Active treatment at the time of the assessment. More than one treatmentoption per patient is possible.

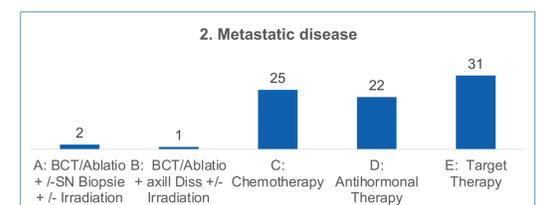


Figure 6. Metastatic disease. Number (N) of patients per subgroup. Active treatment at the time of the assessment. More than one treatmentoption per patient is possible.

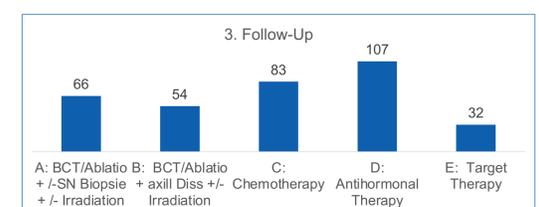


Figure 7. Follow-up group. Number (N) of patients per subgroup. Patients in this group are 6 months - 5 years post-treatment (hormonal Therapy is allowed). Past treatments. More than one option is possible.

Conclusion

In this Phase 4 field study the BR45 module and its scale structure is tested in a large, international group of patients in order to determine its acceptability, reliability, validity, responsiveness and crosscultural applicability. The current sample already consists of a cross-cultural group of patients at different stages of the disease and under different treatment options. A Phase 4 of the study have to confirm psychometric properties of the QLQ BR 45 already done in the Phase 3 necessary to use the module in clinical cancer trials as well as research settings.