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Original Article

Women's Free-text Comments on their Quality of Life: An Exploratory Analysis from the UK Standardisation of Breast Radiotherapy (START) Trials for Early Breast Cancer

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Abstract

Aims: Exploratory analysis of patients' unsolicited written comments in the first 2 years of the Standardisation of Breast Radiotherapy (START) trial quality of life study highlighted a potential effect of non-treatment-related problems on the ratings and interpretation of patient self-reported questionnaires. At 5 years of follow-up all eligible subjects were invited to write comments to further explore these findings.
Materials and methods: Using inductive qualitative methods informed by the exploratory analysis, comments were allocated to relevant themes. Key patient-reported outcome measures (PROMs), clinical and demographic factors were collated for patients who did and did not comment at 5 years and comparisons between the groups explored.
Results: Of 2208 women completing baseline PROMs, 482 proffered comments from 0 to 24 months, forming nine distinct themes, including chronic conditions, life events and psychosocial concerns. At 5 years, 1041/1727 (60.3%) women contributed comments, of whom 500 randomly selected participants formed the sample for analysis. Findings revealed comorbidity, impaired physical functioning and psychosocial problems as key themes, with prevalent adverse effects from local and systemic treatments. Eight new themes emerged at 5 years, including ageing, concerns about future cancer and positive aspects of care. Women commenting were better educated, slightly older and more likely to have had chemotherapy compared with non-commenters. They had significantly worse PROM scores for global health and key quality of life domains relevant to the difficulties they revealed.
Conclusions: Difficult personal circumstances and other health concerns affected many women's PROM ratings at 5 years of follow-up, in addition to ongoing cancer treatment effects. Greater attention to multiple sources of distress and adversity could facilitate personalised care and aid interpretation of PROMs.

Key words: Breast cancer; clinical trials; contextual factors; patients'free-text comments; quality of life; radiotherapy

Introduction

The findings of the Standardisation of Breast Radiotherapy (START) trial's quality of life substudy [1] provided valuable information for patients and clinical teams about beneficial and unfavourable effects of the radiotherapy treatment groups under comparison, as an aid to future decision-making and clinical care provision. START tested a widely used dose regimen (40 Gy in 15 fractions) and two test schedules of hypofractionated radiotherapy (fractions >2.0 Gy) against the international standard of 50 Gy in 25 fractions, in terms of local tumour control and late normal tissue effects. Findings from patients' ratings strengthened the evidence in support of the clinical findings in favour of hypofractionated regimens [2,3], which influenced clinical breast radiotherapy practice [4]. The quality of life findings were derived from standardised measures designed within a biomedical framework, which included questions relating

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to protocol-specific radiotherapy effects that helped distinguish between the regimens.

Such measures are very effective in supporting key end points in clinical trials and cover a range of largely biomedical domains to facilitate multidimensional comparisons between treatment arms and have contributed to clinical improvement. However, they are not designed to encompass non-trial circumstances or individual experiences and so may not inform individual care. There has been extensive psychosocial research detailing the multiple and complex effects of breast cancer and its treatment [5–14], but to date there has been little opportunity for patients to express the meaning or relevance of non-breast cancer symptoms, psycho-social problems or functional limitations in the context of a clinical trial [5,15]. However, it is expected that randomisation will eliminate any bias due to individual circumstances for treatment comparisons in the trial setting.

Unexpectedly, during the first 2 years of quality of life data collection in the START trials, 22% of women wrote unsolicited comments at least once, or enclosed letters, when returning their quality of life booklets. These women frequently wanted to 'explain' that their responses to specific questionnaire items or subscales reflected the effects of other personal problems, life events or health issues rather than breast cancer or its treatment. Some women thought there should be space for such reporting: 'Completing the questionnaire I thought there should be a question about whether there are any factors/worries in your daily life that affect your answers'. These patients also expressed concern that if contextual factors were sufficient to influence their questionnaire ratings they could be misattributed to effects of cancer treatments. The potential value of these comments in raising awareness of contextual problems in the clinical setting and of their possible influence on quality of life ratings warranted further exploration. We therefore conducted a qualitative study of the comments proffered up to 2 years and a summary of the sample composition, analysis and findings is presented as supplementary data in Appendix A. These were found to endorse the importance to quality of life of comorbidity and other contextual factors, not captured by the quality of life measures, and the potential for misattribution of ratings to breast cancer outcomes. If generalised, these contextual factors could lead to inferior quality of life outcomes for long-term survivors in whom the interplay of contextual factors, life stress and ageing may impede adjustment and be detrimental to coping, decision-making and ongoing self-management [16–19].

Following on from this, and given the relatively small sample of women who proffered comments early on in the trial, it was decided to invite comments from all women in the START trials completing patient-reported outcome measures (PROMS) at the 5 year assessment. The aims were: (i) to retrospectively explore reported health concerns and adverse contextual factors and see if they endorsed the proffered comments, and (ii) to examine possible associations between quality of life scores derived from the quantitative questionnaire items and patients' reported health concerns and other adverse contextual factors.

Materials and Methods

Full details of the UK START trials and quality of life substudy have been published separately [1–3]. The START trials were registered as an International Standard Randomised Controlled Trial, number ISRCTN59368779. Patients were recruited to the quality of life study from 31 of 35 radiotherapy centres in the UK between 1998 and 2002 and the main quality of life outcomes were published in 2010 [1]. Ethical approval was obtained from the South Thames Multi-Research Ethics Committee to request additional written comments from all patients completing the 5 year quality of life follow-up assessment; local ethics committees of all participating centres also gave approval. A blank page in the PROMS booklet was included and a patient information letter invited participants to report any health problems or events that they thought might influence the answers they gave in their PROMS booklet (see Appendix B for full text).

The quality of life booklets comprised the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 core questionnaire [20], EORTC QLQ-BR-23 breast cancer-specific module [21], Hospital Anxiety and Depression Scale [22], Body Image Scale [23] and a health economics evaluation [24] for completion at home. The trials office at the Institute of Cancer Research (ICR) first checked the individual's current health status with their hospital team or family doctor before sending questionnaires. Prompts were sent for non-return of questionnaires by letter or telephone 3 weeks after mailing. At 5 years, all pages with comments in the quality of life booklets were logged on the quality of life study database.

The number of comments received on the 5 year questionnaires was too large to analyse using the entire written records and so comments from a random sample of 500 patients were used for the analysis, which followed a constant comparative methodology [25], as described for the proffered comments (Appendix A). Thus, for each patient commenting, each written comment was allocated to an appropriate theme: initially all nine themes created from the proffered comments analyses were used (Appendix A). Additional themes were formed and labelled, for comments that had not previously been submitted. All decisions ascribing comments to 'new' themes were made jointly by at least three coders. Where there was difficulty allocating a theme, a consensus decision was made.

Statistical Methods

Descriptive analyses compared demographic and clinical characteristics, and key quality of life scores between women who did and did not provide comments at 5 years. Quality of life subscale scores at 5 years were calculated as specified in the EORTC scoring manual [26].

A secondary analysis compared quality of life scores in three key domains (global health/quality of life, physical and emotional functioning) and two symptom items (BR23 'hot flushes' and 'worry about future health') for women

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