Short communication

Why patient recorded outcomes should be mandatory in and outside clinical trials to guide management of patients with metastatic breast cancer

Lesley Fallowfield

CRUK Sussex Psychosocial Oncology Group, Brighton & Sussex Medical School, University of Sussex, Falmer, BN1 5JN, UK

Corresponding author: Lesley Fallowfield, L.J.Fallowfield@sussex.ac.uk

Published: 20 December 2007
This article is online at http://breast-cancer-research.com/content/9/S2/S7

Breast Cancer Research 2007, **9(Suppl 2):**S7 (doi:10.1186/bcr1805)

Although metastatic breast cancer (MBC) may be responsive to further treatment, it is incurable, and so improving the quality of life (QoL), not merely the length of life, is an important parameter of benefit. Patients need appropriate formal psychosocial assessment to enable identification of those who may require different forms of support in order to minimize the social and emotional impact of the diagnosis and effects of treatment. Between 31% and 57% of women with MBC will have a mood disorder that merits intervention [1,2], but oncologists are not very skilled at recognizing psychological distress and then referring patients for specialist help [3,4]. This means that patients' psychological needs may go unrecognized, underestimated and undertreated. Some countries may well have resource constraints that limit access to specialist supportive care provided by breast care nurses, trained counsellors, clinical psychologists, liaison psychiatrists and others, but a clear evidence base exists from at least five meta-analyses that demonstrates the efficacy of psychosocial interventions in adult cancer patients [5-9]. In MBC specifically, the benefits of interventions such as group support [10,11] and cognitive behaviour therapy [12] have been demonstrated. The UK and Australia have both produced national guidelines and guidance about the provision of supportive services [13,14].

Patient well being, length of life and QoL must always be the main factors that influence decisions about treatment; however, the accuracy and reliability of clinicians' assessments of well being and QoL in busy clinics is questionable. I have referred above to the difficulty oncologists have in detecting psychological morbidity; some might argue that they are trained in cancer medicine not psychiatry, but how reliable is their detection of other cancer treatment related problems that might influence a patient's well being? Studies show that monitoring of other troubling treatment-related side effects and symptoms is also rather poor when patient recorded outcomes are compared with those recorded by physicians. Observation of oncologists working in busy clinics shows that the manner in which adverse events and side effects are recorded is not especially reliable. For example, even within the relatively tightly controlled setting of a clinical trial, the sensitivity and specificity of the detection of common chemotherapy side effects are unacceptably low [15]. Several other studies have examined the lack of congruence between patient and physician recording of side effects that have an impact on QoL; many are either underestimated or unrecognized altogether by clinicians [16-18]. This is serious because accurate recognition of bothersome side effects could influence the initiation, continuation, change, or termination of therapy, and may prompt timely instigation of other supportive and ameliorative interventions. Information from patient self-report questionnaires may provide a different viewpoint about tolerability and toxicity that is not always recognized as important by health care professionals, and accumulation and discussion of such information enables patients to make more informed choices regarding their treatment options. Some of the side-effects of treatment, especially vasomotor complaints, affect adherence to treatment even in women with advanced disease [19].

Despite the evidence supporting formal data collection, patient self-report assessments still fail to influence management decisions as much as traditional outcomes, such as tumour markers or other objective measures. This is curious given accumulating data from studies in metastatic melanoma, colorectal, lung and breast cancer that demonstrate the predictive and prognostic value of baseline QoL measurement [20]. This predictive information is independent of that derived from other orthodox measures [21]. Studies in patients with advanced breast cancer indicated that regular assessment revealed a decline in QoL scores when disease ceased to respond to chemotherapy, and again this occurred before any indications from other objective measures [22].

Collection of data from formal QoL instruments broadens the parameters of benefit beyond response and survival, and allows a more accurate determination of the supportive and ameliorative interventions that patients with MBC require. The challenge of how to convince clinicians of its value remains. Many worry about the practical difficulties of administering, scoring and interpreting QoL questionnaires, although some researchers have achieved this successfully in their own routine oncology practice [23]. Recently published recommendations from the European School of Oncology have stated the importance of thorough QoL assessment in MBC [24].

It is interesting that the practical and financial burdens associated with measuring tumour markers, despite the questionable utility of these in MBC, do not appear to have been subjected to the scepticism and scrutiny that is reserved for formal measurement of QoL variables.

Acknowledgement

This article has been published as part of Breast Cancer Research Volume 9 Supplement 2, 2007: Controversies in Breast Cancer. The full contents of the supplement are available online at http://breast-cancer-research.com/supplements/9/S2.

References

1. Kissane DW, Grabsch B, Love A, Clarke DM, Bloch S, Smith GC: **Psychiatric disorder in women with early stage and advanced breast cancer: a comparative analysis.** *Aust N Z J Psychiatry* 2004, **38:**320-326.
2. Turner J, Kelly B, Swanson C, Allison R, Wetzig N: **Psychosocial impact of newly diagnosed advanced breast cancer.** *Psychooncology* 2005, **14:**396-407.
3. Passik SD, Dugan W, McDonald MV, Rosenfeld B, Theobald DE, Edgerton S: **Oncologists' recognition of depression in their patients with cancer.** *J Clin Oncol* 1998, **16:**1594-1600.
4. Fallowfield L, Ratcliffe D, Jenkins V, Saul J: **Psychiatric morbidity and its recognition by doctors in patients with cancer.** *Br J Cancer* 2001, **84:**1011-1015.
5. Devine EC, Westlake SK: **The effects of psychoeducational care provided to adults with cancer: meta-analysis of 116 studies.** *Oncol Nurs Forum* 1995, **22:**1369-1381.
6. Sheard T, Maguire P: **The effect of psychological interventions on anxiety and depression in cancer patients: results of two meta-analyses.** *Br J Cancer* 1999, **80:**1770-1780.
7. Newell SA, Sanson-Fisher RW, Savolainen NJ: **Systematic review of psychological therapies for cancer patients: overview and recommendations for future research.** *J Natl Cancer Inst* 2002, **94:**558-584.
8. Rehse B, Pukrop R: **Effects of psychosocial interventions on quality of life in adult cancer patients: meta analysis of 37 published controlled outcome studies.** *Patient Educ Couns* 2003, **50:**179-86.
9. Meyer TJ, Mark MM: **Effects of psychosocial interventions with adult cancer patients: a meta-analysis of randomized experiments.** *Health Psychol* 1995, **14:**101-108.
10. Goodwin PJ: **Support groups in advanced breast cancer.** *Cancer* 2005, **104(suppl):**2596-2601.
11. Classen C, Butler LD, Koopman C, Miller E, DiMiceli S, Giese-Davis J, Fobair P, Carlson RW, Kraemer HC, Spiegel D: **Supportive-expressive group therapy and distress in patients with metastatic breast cancer: a randomized clinical intervention trial.** *Arch Gen Psychiatry* 2001, **58:**494-501.
12. Edelman S, Bell DR, Kidman AD: **A group cognitive behaviour therapy programme with metastatic breast cancer patients.** *Psychooncology* 1999, **8:**295-305.
13. National Institute for Clinical Excellence: **National Institute for Clinical Excellence; Improving supportive and palliative care for adults with cancer.** London, UK: National Institute for Clinical Excellence; 2004.
14. Turner J, Zapart S, Pedersen K, Rankin N, Luxford K, Fletcher J; National Breast Cancer Centre, Sydney, Australia; National Cancer Control Initiative, Melbourne, Australia: **Clinical practice guidelines for the psychosocial care of adults with cancer.** *Psychooncology* 2005, **14:**159-173.
15. Fromme EK, Eilers KM, Mori M, Hsieh YC, Beer TM: **How accurate is clinician reporting of chemotherapy adverse effects? A comparison with patient-reported symptoms from the Quality-of-Life Questionnaire C30.** *J Clin Oncol* 2004, **22:** 3485-3490.
16. Fellowes D, Fallowfield LJ, Saunders CM, Houghton J: **Tolerability of hormone therapies for breast cancer: how informative are documented symptom profiles in medical notes for 'well-tolerated' treatments?** *Breast Cancer Res Treat* 2001, **66:**73-81.
17. Coombes RC, Bliss J, Hall E, Gibson L, Fallowfield L, Massimini G, for the Intergroup Exemestane Study: **Under-reporting of symptoms in patients with early breast cancer who have received tamoxifen treatment for 2-3 years [abstract].** *Proc Am Soc Clin Oncol* 2003, **22:**48.
18. Savage C, Pater JL, Tu D, Norris B: **He said/she said: how much agreement is there on symptoms between common toxicity criteria and quality of life? [abstract].** *Proc Am Soc Clin Oncol* 2002, **22:**1540.
19. Cox AC, Fallowfield LJ, Jenkins VA: **Communication and informed consent in phase 1 trials: a review of the literature.** *Support Care Cancer* 2006, **14:**303-309.
20. Fallowfield L: **Quality of life: a new perspective for cancer patients.** *Nat Rev Cancer* 2002, **2:**873-879.
21. Coates A, Poezsolt F, Osoba D: **Quality of life in oncology practice: prognostic value of EORTC QLQ-C30 scores in patients with advanced malignancy.** *Eur J Cancer* 1997, **33:**1025-1030.
22. Fraser SC, Ramirez AJ, Ebbs SR, Fallowfield LJ, Dobbs HJ, Richards MA, Bates T, Baum M: **A daily diary for quality of life measurement in advanced breast cancer trials.** *Br J Cancer* 1993, **67:**34-36.
23. Velikova G, Booth L, Smith AB, Brown PM, Lynch P, Brown JM, Selby PJ: **Measuring quality of life in routine oncology practice improves communication and patient well-being: a randomized controlled trial.** *J Clin Oncol* 2004, **22:**714-724.
24. Cardoso F, Winer EP, Fallowfield L, Namer M, Pagani O, Rodenhuis S, Senkus-Konefka S, Wardley A, Costa A: **Guidelines, metastatic breast cancer. Recommendations from the European School of Oncology- MBC Task Force.** *The Breast* 2007, **16:**9-10.