

Overview

Quality of Life and Patient-reported Outcomes in the Older Breast Cancer Patient

R. S. Ballinger, L. J. Fallowfield

Cancer Research UK Psychosocial Oncology Group, Brighton and Sussex Medical School, University of Sussex, Brighton, UK

ABSTRACT:

As the world population ages, the incidence of cancer will probably also increase as it is a disease predominantly affecting older people. However, those aged 70 years or more have largely been excluded from clinical trials. This review focuses on breast cancer. Increasingly there is recognition that many older breast cancer patients are being undertreated and could and should be offered the same treatments as younger patients. Comprehensive assessment of the quality of any survival benefit from treatments is also needed to ensure that in the future older patients can make fully informed decisions about their treatment options. The aim of this overview is two-fold: first to describe methods by which to assess quality of life; and second to review the recent surgical, radiotherapy, chemotherapy and other studies that include such assessment with older breast cancer patients. Current studies are also outlined, including quality of life assessments, and recommendations are made for future research in this area. Ballinger, R. S., Fallowfield, L. J. (2009). *Clinical Oncology* 21, 140–155

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Key words: Breast cancer, older patient, patient-reported outcomes, quality of life, review

Statement of Search Strategies Used and Sources of Information

Several Medline searches were undertaken in November 2007, and automatic alerts for subsequent publications arranged. The following keywords were used, with limits shown in parentheses: cancer quality of life (review; aged 65+ years; 80+ years; English language; published within the past 3 years); breast cancer quality of life patient related outcomes, breast cancer quality of life older, breast cancer quality of life (published in the last 5 years; female; aged 65+ years; 80 and over: 80+ years); quality of life breast cancer trial older (published in the last 5 years; clinical trial; randomised controlled trial; aged 65+ years; 80 and over: 80+ years); quality of life breast cancer trial elderly (published in the last 5 years; clinical trial; randomised controlled trial; aged 65+ years; 80 and over: 80+ years); breast cancer quality of life older elderly OR breast cancer quality of life older (publication date > 1996). Internet searches of active studies in trial portfolios were also undertaken. Further references were obtained through papers cited elsewhere and from the authors' collections.

Introduction

The proportion of the world population aged over 60 years has risen from 8% in 1950 to 11% in 2007 and is expected to

reach around 22% in 2050 [1]. This has significant implications, not least of all in terms of cancer incidence as a disease that predominantly affects older people. For instance, 59% of people diagnosed with cancer in the European Union are aged over 65 years (estimates in year 2000) [2]. Similarly, data from 17 areas in the USA in 2005 show that the incidence of breast cancer diagnosis in those aged <50 years was around 41 per 100 000, whereas for those aged 75+ years it was around 402 per 100 000 [3]. Each year in the UK more than 44 000 women are diagnosed with breast cancer and 80% of these are women over the age of 50 years [4]. Despite increased long-term survival of breast cancer, more than 12 000 women die from it each year in the UK and more than half of those are women aged over 70 years [4]. However, those aged 70+ years are usually excluded from clinical trials. This means that the efficacy of treatments in the older age group is largely unknown, consequently treatment decisions rest on individual preference and biases. Older women may, for instance, be denied chemotherapy due to the assumption that they are too frail or that the side-effects would be too much of a burden.

The International Society of Geriatric Oncology recently concluded that there is a need to develop prospective clinical trials for the older patient population with breast cancer [5]. The absolute harms and benefits of treatments is critical to know because protecting quality of life (QoL) is arguably crucial in older persons with more limited life expectancy than in younger persons [6]. Two concepts are

important to define clearly and consider here. First, what might previously have been described as QoL is now increasingly referred to as patient-reported outcomes [7,8]. Patient-reported outcomes may measure, via standardised and self-report questionnaires, a number of parameters related to the patient's self-reported health status and perception of treatment effects, including QoL, symptom severity and symptom impact [9]. The second concept is the definition of 'elderly' or 'old age', which may vary between studies. For instance, the International Society of Geriatric Oncology used an 'arbitrary threshold of 60 years' to obtain sufficient studies to make their recommendations for diagnosing and treating breast cancer in the elderly. However, they acknowledged that the International Conference of Harmonisation Good Clinical Practice definition of elderly is 65+ years [5]. It is generally well recognised that older patients are a heterogeneous group, and that functional and cognitive abilities may be a more useful indicator about suitable therapeutic options than chronological age.

Increasingly there is recognition that many older breast cancer patients are being undertreated and could and should be offered the same treatments as younger patients [10,11]. More information about the effect on patient well-being, as well as efficacy, of anti-cancer treatment will assist decision-making. For instance, a review of prostate cancer studies found that although 54% of the identified studies did not show any differences in clinical end points between treatment groups, 74% of the studies showed some QoL difference [12]. Similarly, a review of 33 surgical oncology trials that included QoL assessment found that 22 had concluded that QoL outcomes influenced treatment decisions or provided valuable data about informed consent [13]. Comprehensive assessment of the quality of any survival benefit from treatments is also needed to ensure that in the future older patients can make fully informed decisions about their treatment options. Communication is an essential issue in this regard. One review [14] considered the evidence showing that older patients may prefer and rely on physician-initiated QoL discussions [15]; and that those who perceived that their physicians had asked 'caring' questions were twice as likely to report that they had a choice of treatment [16]. Exercising such choice has been claimed to result in health benefits [17]. Having the health-related QoL implications of different therapeutic options explained seems crucial for appropriate decision-making. However, a review of 24 European Organisation for Research and Treatment of Cancer (EORTC) trials using the EORTC QoL measures [18], found that only one was concerned with breast cancer and the elderly [19]. A few other reviews have also been published in recent years about QoL in older patients with cancer generally [20–22], breast cancer specifically [6,23], and of breast cancer treatments [24,25]. The aim of this overview is to describe QoL methods, and to review the recent surgical, radiotherapy, chemotherapy and other studies that are wholly or in part concerned with QoL assessments in older breast cancer patients.

Quality of Life and Patient-reported Outcomes

QoL is a somewhat broad concept that is often used rather loosely in clinical publications and decision-making. However, there are specific standardised clinical assessments that are of value both in the clinic and research setting. For instance, the Comprehensive Geriatric Assessment was developed primarily for diagnostic purposes, planning of individual care and quality assurance [22], but it includes measurements that relate to QoL. It is claimed that the Comprehensive Geriatric Assessment enables discernment of at least three stages of ageing with different risks of therapeutic complications: those who are functionally independent without co-morbidities, who could be offered standard cancer treatment; those who are frail for whom only palliative treatment may be applicable; and people in between, who may benefit from a particular special pharmacological approach such as dose reduction [26]. Such categorisations may also be useful for research purposes. Administration of QoL measures for some older patients may be difficult due to co-morbidities and functional problems such as failing eye sight, hearing, arthritic hands as well as impaired cognitive functioning. Some of the items or questions may also be of little relevance to an older population. Developing specialised tools, such as the use of multiple informants [14], may be necessary so that older people are not excluded from trials. Similarly, a review of health outcomes generally for older people with cancer referred to the potential of a 'user-generated approach' [27] and attempts are being made to develop geriatric assessments for use specifically with older cancer patients [28]. Further methodological problems and recommendations in generally assessing QoL in older patients are discussed elsewhere [29,30].

Some individual domains related to well-being and functioning can be considered separate from and then compared with specific QoL measures. For example, one review considered age, functional status, mobility, anaemia, co-morbidity, depression and dementia and their influence on QoL in cancer patients [22]; and in another the functional status of cancer survivors was considered separately from QoL [21]. However, QoL also refers to specific measures that have been developed, mainly for use within clinical trials. Increasingly there are calls for the use of these measures in clinical practice [31].

QoL measures, such as the Functional Assessment of Cancer Therapy (FACT), comprise questions about physical, social, emotional and functional well-being; with additional add-on questions as required for particular studies, e.g. about endocrine symptoms or the effect of taxanes. QoL measures were largely developed and validated with younger or mixed age populations, so it is important to establish that they are appropriate for older patients too. Table 1 gives examples of types of assessment with information about sensitivity to age.

A systematic review of 37 QoL studies of older patients with various illnesses found that the Short Form (36) Health Survey

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