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Quality of life and health status in breast carcinoma

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KEYWORDS

Quality of life; Health status; Questionnaires; Breast cancer; Surgery **Abstract** Quality of life is of increasing importance in clinical oncology studies. When analysing publications concerning quality of life in breast cancer, however, the majority of the articles appear to study health status and not quality of life. Therefore five recommendations were formulated to apply reading a 'quality of life' article. With the use of these recommendations an article can be evaluated and the clinical significance can be assessed.

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Introduction

In many clinical oncology studies Quality of life (QoL) is an important outcome measure. However, interpretation of the published results can be difficult because of a large range of questionnaires used and considerable variation in study design.

In the Netherlands, one in every 10 women will develop carcinoma in situ or invasive carcinoma of the breast during her life. In the late 1970s and early 1980s several prospective clinical trials showed that breast conserving surgery (i.e., lumpectomy and axillary lymph node dissection; BCS) followed by radiotherapy was equivalent to modified radical mastectomy (MRM) concerning 5-year survival and disease-free survival. Since these publications, women with early breast cancer participate increasingly in treatment decisions. QoL is an important factor in this process, because

Quality of Life

Quality of Life

Quality of Life is defined by the World Health Organisation Quality of Life Group as 'an individual's perception of his/her position in life in the context of the culture and value systems in which

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it is thought to be influenced by the type of treatment the patient receives. When a surgeon wants to advise his patients about the (dis)advantages of the two surgical treatment modalities, it is important to have some knowledge of the results of QoL studies in breast cancer. The purpose of this article is to evaluate recent QoL studies and provide insight in the methods and questionnaires used to evaluate breast cancer patients' QoL. Recommendations concerning the interpretation of the published results are formulated and the clinical significance of the evaluated studies will be determined using these recommendations.

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he/she lives and in relation to his/her goals, expectations, standards and concerns'. In other words, QoL is a person's evaluation of his/her functioning in a wide range of areas. This definition implies that QoL is subjective and can therefore only be judged by individuals themselves.

Health status

In medical literature, the term QoL is often used simultaneously with the terms health-related quality of life (HR-QoL) and health status (HS). Frequently these three terms are considered interchangeable. However, HS and HR-QoL can be grouped together but are not equivalent to QoL. HS refers to 'the defined well-being in terms of physical, mental, and social condition or function'.⁵ Thus, HS measures the impact of disease on functioning⁶ and patients are asked solely about their physical possibilities, social activities, and state of mind and not about their feelings concerning their functioning. Therefore, HS indicates whether there are limitations whereas QoL also reflects to what extent a patient is bothered by these limitations in daily life.

Questionnaires

The structure of HS and QoL questionnaires is based on the definition of health by the WHO being 'a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity'. Therefore, the questionnaires have three principal domains: the physical domain, the psychological domain, and the social domain.8 For HS questionnaires the physical domain refers to bodily function or its impairment. The psychological dimension refers to negative effects on the psychological functioning, for instance, mood disturbance and level of distress. The social aspect refers to the ability to perform the daily social role, for example, in the relationship with partner, family, or friends. In QoL instruments patients are also asked about their perception or evaluation of their functioning in these domains. Another important difference is the construct of the questions. HS questionnaires tend to phrase their questions negative (e.g. Are you limited in any way in doing either your work or doing household jobs? No/Yes)⁹ and explore a limited number of aspects whereas QoL instruments usually cover more aspects and contain negative and positive stated questions (e.g. To what extent do you feel that physical pain prevents you from doing what you need to do? Not at all/A Small amount/A Moderate amount/A Great deal/An Extreme amount). 10

Most of the HS and QoL questionnaires are generic, implying that the questionnaire was developed for a general healthy and ill population and not for a defined selection of individuals. These generic questionnaires can be supplemented with disease-, symptom-, or treatment-specific modules.¹¹

Methods

A literature search using MEDLINE and psychINFO was performed to analyse recent QoL research concerning early-stage breast cancer. As search item 'quality of life' was used together with 'breast neoplasms', 'mastectomy', and 'breast conservation'. The references of the articles retrieved through this search were surveyed and additional studies were identified. The search covered the period from January 1985 until July 2003. The articles had to be written in English. Furthermore, an article had to focus on the physical, psychological, and social aspects. The authors strongly feel that all three domains of QoL and HS should be taken into consideration when reaching a judgment about the QoL or HS of an individual patient or cohort of patients.

The search resulted in 33 articles. After applying the selection criteria on these articles and their reference articles, 20 studies remained (see Table 1). The HS and QoL questionnaires used in these studies will be discussed in terms of their design and what they measure.

Methodological criteria

HS or QoL questionnaires should meet three methodological criteria to be considered a useful instrument: reliability, validity, and responsiveness to change.³²

Reliability

The key types of reliability in this context are internal consistency and test-retest reliability. Internal consistency refers to the homogeneity of questions in a (sub)scale. Each scale in a certain questionnaire represents a factor of interest, such as psychological functioning. Body image is an example of a subscale within the psychological domain. Depending on the number of questions in a (sub)scale, internal consistency (Crombach's alpha)

Table 1					
Author	Study design	Number of questionnaires	Type of questionnaires	Frequency of testing	Moment of testing
Schain 1983 ¹²	Retrospective	1	QoL	1	10 m po
De Haes 1985 ¹³	nm	1	HS	1	11 m po
De Haes 1986 ¹⁴	nm	1	HS	2	11 m 18 m po
Levy 1989 ¹⁵	Retrospective	2	HS	2	3 d, 3 m po
Ganz 1992 ¹⁶	Prospective	5	HS	4	1 m, 3 m, 6 m, 12 m po
Levy 1992 ¹⁷	Prospective	3	HS	3	pre-op, 3 m, 15 m po
Hughes 1993 ¹⁸	Prospective	4	3x HS, 1xQoL	2	pre-op, 2 m po
Shimozuma 1995 ¹⁹	Prospective	1	HS	4	pre-op, 0-2 m, 3-12 m, 13-24 m po
Ganz 1996 ²⁰	Retrospective	5	HS	2	2 y, 3 y po
Gilbar 1997 ²¹	Retrospective	1	HS	1	3-7 m po
Dorval 1998 ²²	Prospective	4	HS	3	3 m, 18 m, 8 y po
Jahkola 1998 ²³	Retrospective	2	QoL	1	3-8 y po
Pusic 1999 ²⁴	Retrospective	2	HS	1	3 y po
Wapnir 1999 ²⁵	Retrospective	1	HS	1	1-7 y po
Cohen 2000 ²⁶	Retrospective	2	HS	n.m.	1-5 y po
King 2000 ²⁷	Prospective	3	HS	2	3 m, 12 m po
Rowland 2000 ²⁸	Retrospective	6	HS	1	1-5 y po
Holzner 2001 ²⁹	Retrospective	2	HS	1	4-7 y po
Janni 2001 ³⁰	Retrospective	1	HS	1	46 m po
Nissen 2001 ³¹	Prospective	3	HS	7	pre-op, 1, 3, 6, 12, 18, 24 m po

Note: nm, not mentioned; QoL, Quality of Life; HS, Health Status; pre-op, pre-operative; po, post-operative; d, days; m, months; y, years.

should be at least 0.70. To measure test-retest reliability repeated assessments evaluating an unchanged characteristic are carried out. A test is considered reliable when the reliability coefficient is above 0.80 in a test-retest set-up.³³

Validity

Validity implies that a test measures what it is supposed to measure and refers to the degree of non-random or systematic bias.³⁴ Validity can be determined in different ways. First, there is the inter-scale correlation for questionnaires that consist of various scales. The scores of conceptually related scales (e.g., physical functioning and fatigue) correlate substantially with each other. This is called construct validity. Second, the scores of a questionnaire need to be able to discriminate between subgroups of patients differing in clinical status, called discriminant validity.³⁵ The responsiveness of a test (also known as clinical validity) is the sensitivity of a test to changes in QoL/HS over time or after an intervention, such as treatment.³⁶

In addition to these methodological criteria, instruments need to be self-administered since it

is known that physicians or spouses tend to either underestimate or overrate the QoL of patients.³⁷ The questionnaire has to be multi-dimensional covering the physical, psychological, and social domain, relatively brief (taking less than 15 minutes to complete), and have a good acceptability to patients.³⁴ To ensure that measurements are comparable after translation of a questionnaire, semantic equivalence has to be achieved. To this extent standardized translation procedures using forward and back translations have been formulated.¹¹

Number of questionnaires used in a study

In the selected articles the number of questionnaires varies from one 12-14,19,21,25,30 to six. 28 When researchers applied more than one questionnaire, each test was focused on one specific domain of QoL/HS. The authors then tend to base general conclusions concerning the QoL/HS of the patients on a combination of the different scores. Combining the scores however, may not justify the outcome of each individual QoL/HS questionnaire. Furthermore, it is important to use the appropriate questionnaire for the posed hypothesis. Kemmler et al. showed in their study that two HS questionnaires applied to the same study group gave completely different results and were not interchangeable. ³⁸ Usually the specific characteristics of a questionnaire can be found either in the reports describing the initial development and testing of the instruments or in the manuals.

Type of questionnaires

The first step in analysing the results is to determine whether questionnaires used measure HS or QoL. A HS questionnaire solely measures the presence of impairment in each of the three domains, whereas a QoL questionnaire asks about satisfaction. When a patient is not capable to walk the stairs without difficulty she will have a low score in the physical domain in a HS questionnaire. However, when the same patient is not bothered at all by this problem she will score normal in a QoL questionnaire. So the same impairment can lead to completely different scores for HS and QoL and, thus, to completely different results and conclusions. Therefore, the type of questionnaire has to be in line with the aim of a study. Another important factor influencing the outcome of HS and OoL instruments is how the questions are phrased. HS questionnaires tend to formulate their questions negatively which may result in more pessimistic answers from the patient. QoL questionnaires use positive and negative formulations, thus preventing a negative trend in the answers.

Study design

Breast cancer is in the majority of patients not a fatal illness, but a chronic disease that often requires treatment over the course of months or even years with complex and toxic therapies. Several studies measure the development of QoL/HS over time. When statements are made about the course of QoL/HS it is important to have a clearly defined starting point, preferably before treatment commences. Thus, the study design needs to be prospective.

In many cases QoL/HS is only one of the outcome measures in a study. It is known that patients participating in clinical trials have a better prognosis, presumably because of standardized care or due to particular selection criteria for trial participation.³⁹ One could argue that this better prognosis

and the attention given to the patients because of their participation in a study in itself results in a better QoL/HS. It is important that this possible bias is acknowledged.

Frequency and moment of testing

In general, when breast cancer is diagnosed, QoL is negatively influenced. Surgical treatment and adjuvant radiotherapy or chemotherapy also have a profound negative influence on the reported QoL/HS. 40-42 When treatment results in disease-free survival women tend to become less concerned and QoL/HS improves. In essence, 'time heals all wounds'. This phenomenon is also known as response shift. When researchers are interested in the course of QoL/HS over time the questionnaires need to be administered more than once and over a longer period of time. Because of the large impact of treatment and adjuvant treatment on QoL/HS timing of questionnaire completion must be carefully considered.

Recommendations

Based on the aspects of QoL/HS studies presented above we suggest the following recommendations for the interpretation of the results of such studies:

- Determine whether QoL is your subject of interest or merely the functional consequences of breast cancer treatment. For the latter HS studies are sufficient.
- Check the keywords for QoL and HS to determine in which category the authors place their research.
- 3. Analyse the hypothesis of the researchers and ascertain the goal of the study. Do the authors wish to establish impairment of functioning or are they interested in the satisfaction of their research population with their functioning. Verify that the hypothesis is represented correctly by the choice of keywords.
- 4. Make sure that the study design is able to confirm the hypothesis of the article. When the authors wish to establish a certain development of QoL/HS over time the study design needs to provide repeated measurements and an adequate follow-up period. Ascertain whether QoL/HS is the main outcome measure or part of a larger research question as this may influence the reported results.
- 5. Evaluate the questionnaires used. Did the authors use an appropriate questionnaire to

examine their hypothesis? When the article is categorized as a QoL study, make sure that only QoL questionnaires are used. What is the number of questionnaires used and are the authors able to explain why these specific questionnaires were used. Make sure that the results of different questionnaires are discussed separately and not combined to reach one general conclusion.

When these recommendations are followed, we feel that the reported results are useful for a surgeon when advising patients with early-stage breast cancer.

Analysis of the selected articles

The 20 selected articles that met the selection criteria are now analysed using the aforementioned recommendations to determine their clinical usefulness.

Recommendation 1

We were interested in QoL studies, HS was not used as a search item in our initial search. When, in retrospect, HS is added to the search list one additional article is found. 43 So, although the majority of these studies are HS studies this key word is seldom used.

Recommendation 2

Nine of the included articles used QoL as a keyword, ^{17,19,21,22,25-27,30,31} but none actually used QoL questionnaires and therefore these studies cannot be categorized as QoL studies. The three studies that did apply QoL questionnaires ^{12,18,23} did not use QoL as a keyword. None of the included articles used Health Status as a keyword, even though 17 of the 20 studies used only HS questionnaires. So, concerning recommendation 2 we conclude that most often the key words HS and QoL do not reflect the content of the study.

Recommendation 3

The majority of the included articles are descriptive studies without an apparent hypothesis. Four studies are based on a hypothesis concerning the effect of surgical treatment of breast cancer on the QoL of the patients. ^{13,21,25,26} These studies, however, have not used QoL questionnaires to examine the hypothesis.

Recommendation 4

The studies varied largely in design. Of the four articles based on a hypothesis, one reported the first results of a longitudinal study, therefore its conclusions may change over time. ¹³ In another study, the issue of QoL was a secondary aim and although the authors felt that time since surgery is a factor of influence, they did not mention a time frame in the study design. ²⁶ Two articles assumed that BCS resulted in a better QoL and verified this hypothesis by using HS questionnaires which were applied only once to the patients in a retrospective setting. ^{21,25}

Fifteen articles were descriptive studies. The authors either determined the development of HS/QoL over time depending on the treatment received by the patient^{14-19,22,29,31} or compared HS/QoL for two treatment modalities (MRM and BCS) at certain moment after treatment. ^{12,23,24,30} In two descriptive studies, patients were divided in study groups based on time since surgery. The women received the questionnaires only once, but at different time frames after surgery. Conclusions were then drawn concerning the development of HS over time. ^{28,29}

Seven studies were retrospective in nature 12,15,23,24,28-30 and in two of them the HS/QoL issue was added in hindsight to an already existing research protocol. 12,15 HS/QoL was one of the study outcome measures and not always the primary research question in seven of the included studies. 14,16,17,23,24,30,31 It was the sole outcome of interest in six articles. 18,19,22,27-29 When HS/QoL was not the only outcome measure of interest, the reported results may have been influenced positively by the extra attention paid to the patients during the study and the fact that treatment followed a strict protocol. None of the authors took this confounding factor into consideration.

When statements were made about HS/QoL over time a baseline measurement, preferably before surgery, should have been included in the study. Only four studies had a baseline measurement. ^{17-19,} ³¹ The other studies that applied the questionnaires more than once started post operative and the timing of the first measurement seemed ad random.

Recommendation 5

Table 1 shows that only three studies used QoL questionnaires, either as the only questionnaire^{12,23} or in combination with HS questionnaires. However, all 20 studies are described as QoL-research. Seven studies used one questionnaire to assess

HS or QoL, in the other the number of questionnaires varied from two to six. All authors claimed that the questionnaires used in their study were QoL instruments. Most authors explained the purpose of the questionnaire and the specific domains assessed. However, in most articles the psychometric qualities of the questionnaires used were not specified or even mentioned. Thus, the quality of the questionnaires used could not be established when reading the articles.

Finally, all studies that used more than one questionnaire combined the results of the individual questionnaires to reach a general conclusion about HS/QoL.

Conclusion

After evaluation of the included articles using the aforementioned recommendations we feel that none of these studies is a genuine Quality of Life study that truly examines the development of QoL over time after surgical treatment for breast cancer. Therefore, one should be careful to ground clinical advice to individual patients concerning their treatment on these 'QoL' studies.

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