

Health-Related Quality of Life Questionnaires in Breast Cancer Patients. A Comparative Study Plus Systematic Literature Review

Stavrakis T^{1*}, Foroglou P² and Papapolichroniadis C³

¹Resident in Obstetrics-Gynecology, 3rd Department of Obstetrics & Gynecology, Medical School, Aristotle University of Thessaloniki, UK

²Assistant professor in Plastic Surgery, Plastic Surgery Department, Medical School, Aristotle University of Thessaloniki, UK

³Associate professor MD PhD, 1st Propedeutic Surgical Department, Medical School, Aristotle University of Thessaloniki, UK

***Corresponding author:** Thomas Stavrakis, Resident in Obstetrics-Gynecology, 3rd Department of Obstetrics & Gynecology, Medical School, Aristotle University of Thessaloniki, NW3 2QH, London, United Kingdom, E-mail: tstavrakis@gmail.com

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Abstract

Background: Breast cancer is the most common cancer in women globally as well as the principle cause of death. Despite the high incidence rates of this malignant disease, 89% of women diagnosed with breast cancer are still alive more than 5 years after their diagnosis. This outcome is due mainly to early diagnosis and treatment design with or without reconstructive aesthetic procedure. Satisfaction and seriously quality of life is the most important point of view in our systematic and extensive research study of international literature.

Materials and Methods: We reviewed totally 31 studies containing a large number of different instruments measuring health related quality of life in breast cancer treatment, with or without reconstruction.

Results: Overall, 24 different survey instruments were identified within the 31 included studies. The most frequently used questionnaires are SF-36 and then FACT-B and most studies used more than 1 questionnaire.

Conclusions: The SF-36, FACT-B, EORTC-C30 and EORTC BR23 are most common questionnaires used in assessing health related quality of life in breast cancer. Suitable and correct approach to the patient is one of the best and important factors of the research. The patients feel comfortable of this reality from researcher's interest so by this correct contact express their experience and opinions about disease treatment design.

Keywords: Breast Cancer; Mastectomy; Health-Related Quality of Life; Questionnaires; Breast Reconstruction

Introduction

What is (Health-related) quality of life?

The term Quality of Life (QOL) is used to refer to an individual's total wellbeing and it includes all emotional, social, and physical aspects of the person's life. In medicine we use to say Health Related Quality of Life (HRQOL), in an effort to describe how the person's wellbeing may be influenced by a disease, a disability, or a disorder.

The World Health Organization has defined quality of life as "an individual's perception of their position in life in the context of the culture and value system in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships and their relationships to salient features of the environment."

Donovan et al. citing Campbell suggested as an general definition of quality of life "a person's subjective sense of well-being, derived from current experience of life as a whole" [1,2]. Goodinson and Singleton described quality of life as "the degree of satisfaction with perceived present life circumstances" [3]. According to Bergner quality of life rises as the distance between achieved and desired ambitions diminish [4].

Quality of life includes both objective and subjective factors that affect person's well being. Money income, education and health status are the primary objective factors, while subjective factors include individual's satisfaction with education, income and conditions of living. Quality of life refers to a subjective estimation of the fulfillment of a person's wishes, needs and goals. Quality of life is a complex approach consisting of three main components: physical, emotional and social functioning. The first two elements are clearly linked to health-related quality of life. Many researchers consider that social functioning is out of the scope of the health domain. However according to the World Health Organization quality of life is an all-inclusive concept including all factors that influence an individual's life, even if those factors are external to health domain, such as political, cultural, aesthetic, economic and environmental aspects of a person's existence. Health-related quality of life contains those factor linked to an individual's health.

The project of Quality of Life measuring in health has been provoked by the need to assess the impact and consequences of clinical therapies and to control the relative benefits of rival health programs. Nowadays it is necessary to go beyond the classical old measures like number of successfully treated patients.

Bergner was one of the first researchers noted that patient's life was affected by side-effects of a treatment and hence it is crucial to assess all treatments consequences [4]. In the same context, Revicki compared three anti-hypertensive medicines, based also on their effect on patient's quality of life, considering their side-effects on general well-being, sleep, sexual ability, social activity and psychological status. The drugs had almost equal efficacy in blood pressure, but their side-effects on physical well-being of the patients varied [5].

Health-related quality of life is best measured via instruments that asses the dimensions found to affect HQOL and combine them into a single index. The instruments to measure such a multidimensional and partial subjective term are the Quality of Life Questionnaires. The concept is based on self-reported measures that combined can help the scientist to assess the person's Quality of Life.

Breast Cancer and treatment strategy

Breast cancer is the most common cancer in women worldwide. It is also the principle cause of death from cancer among women globally. Despite the high incidence rates, in Western countries, 89% of women diagnosed with breast cancer are still alive 5 years after their diagnosis, which is due to detection and treatment [6].

The UK and USA have one of the highest incidence rates worldwide (together with the rest of North America and Australia/New Zealand), making these countries a priority for breast cancer awareness [6].

In the modified radical mastectomy the entire breast is removed, (skin, areola, nipple, and most axillary lymph nodes), sparing the pectoral is major muscle.

Complications originating from modified radical mastectomy include wound healing issues, such as skin necrosis, infection, chronic seroma, dehiscence and hematoma.

There is a risk of anaphylaxis for patients who prior to axillary dissection undergo sentinel lymph node biopsy

and it is related to the isosulfan blue contrast agent. This rare complication often resolves intraoperatively [7].

The risk of developing lymphedema is high in patients who have undergone a complete axillary dissection. Chronic pain in that area, numbness under the axilla and hypersensitization are also complications of axillary dissection.

The post-mastectomy cosmetic result may cause concern to the patients, considering the change in the appearance of their breast(s). Breast reconstruction is possible for the majority of patients after mastectomy. Often, patients who are going to undertake a modified radical mastectomy may be candidates to undergo breast reconstruction surgery during the same procedure.

There has been conducted no large-scale prospective randomized trial to compare the benefits and safety of immediate vs. delayed reconstruction. In 1984 Webster et al reviewed the results of their first 85 immediate reconstructive procedures following mastectomy for breast cancer, obtaining acceptable cosmetic results in most patients with no mortality or life-threatening morbidity. A number of problems concerning the trauma and the prostheses were observed which decreased with increasing experience. The blood transfusion requirements and operating time were increased. There was no prejudicial effect on tumor behavior was observed when assessed as part of a case-control study [8]. Overall survival, local relapse and distant recurrence were equal, in the different the reconstructed cases and unreconstructed controls, suggesting that immediate reconstruction was safe [8].

In a small randomized trial conducted in Edinburgh (1983), immediate and delayed reconstruction was compared with psychosocial morbidity being measured in both groups [3]. For those who had immediate reconstruction, there were significant advantages in terms of return to work, freedom with dress and self-image. Al-Ghazal et al. [4] Interviewed 121 patients after a mean of 5 years after either immediate or delayed reconstruction. Of those who had immediate reconstruction, 95% said that they preferred this approach, whereas 76% of those who had delayed reconstruction wished that an immediate operation had been possible. In terms of anxiety and depression, this was less in those who had immediate reconstruction, and body image and self-esteem were better in this group.

Wellisch et al. evaluated two groups of patients from different plastic surgeon populations to compare the psychosocial conditions between those who underwent immediate versus delayed breast reconstruction. The cosmetic outcome was the same in the two groups, but the experience of living with the post mastectomy deformity in the group of delayed reconstruction diminished the level of satisfaction resulting in better psychological scale results [9].

The increasing number of treatment alternatives and the declining differences in cost of surgeries and clinical effectiveness make the importance of consistent and comparable health-related quality of life (HRQOL) parameters grows - both for medical and health financial evaluation.

The main survey instrument used in all the researches measuring the health related qualities of life are the Questionnaires. In this paper we are analyzing the questionnaires that are most frequently used in the medical projects evaluating and comparing the quality of life of patients who underwent modified radical mastectomy, followed or not by immediate or delayed breast reconstruction.

The questionnaire based survey for measuring health-related quality of life has become typical.

Material and Methods

We searched the PubMed database for manuscripts researching health-related quality of life in breast cancer patients, followed or not by mastectomy and breast reconstruction. We reviewed their survey instruments and their results.

A total of 31 studies were reviewed as it is presented in (Table 1). The several questionnaires are briefly analyzed in this text of our review study. These series of questionnaires are recorded in (Table 2) in abbreviation terms.

Questionnaires of European Organization for Research and Treatment of Cancer (EORTC)

EORTC QLQ C-30: The EORTC QLQ-C30 is a 30-item self-reporting questionnaire developed to measure the quality of life of cancer patients. The QLQ-C30 Version 3.0 is the most recent version. It is composed by five subcategories of questions (role, physical, cognitive, emotional and social functioning). Fatigue, pain, and nausea and

vomiting are also three assessed in three multi-item symptoms scales and there also questions about common symptoms of cancer patients. This questionnaire is copyrighted and has been translated and validated into 81 languages.

EORTC QLQ BR-23: The BR-23 is the questionnaire produced by EORTC targeting Breast Cancer Patients. It is a 23-item breast cancer-specific questionnaire consisting of three symptom scales (arm issues, breast symptoms, and systematic therapy side effects) and two functional scales (body image satisfaction and sexual functioning) and. Sexual satisfaction and hair loss consequences are also measured through the rest of the questions.

Body Image Scale (BIS)

A 10-item scale was constructed by P. Hopwood et al in collaboration with the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Study Group [10]. The scale was designed to be used to patients with any cancer site and any form of cancer therapy.

Body Image Scale interferes with the psychological effects of body alterations created by cancer disease, chemotherapy, radiotherapy and surgery. The patients report his feelings about the cosmetic results of his therapy.

The Hospital Anxiety and Depression Scale (HADS)

A.S. Zigmond and R. P. Snaith created the scale to assess the emotional disorder of patients [11]. The HADS is a fourteen item scale that generates ordinal data. Half items are measuring anxiety and the other half depression. Each item on the questionnaire is scored from 0-3 thus the total score of a person can vary between 0 and 21 for either anxiety or depression [12].

Functional Assessment of Cancer Therapy-Breast Quality-of-Life Instrument (FACT-B)

This is a self report questionnaire created to measure multidimensional quality of life in breast cancer patients and it is consisted of FACT-General (FACT-G) and the Breast Cancer Subscale (BCS), which is focused on breast cancer complications and side effects [13]. The Functional Assessment of Cancer Therapy-General (FACT-G) scale, was designed and validated by Cella et al. [14] in the USA, is widely used to measure HRQOL in cancer patients. The latest version 4 of FACT consists of a total of 27 items

separated into separate subscales: physical (seven items), emotional (six items), social/family (seven items) and functional (seven items) well-being. Patients respond to each question with a score of 0–4, where 0 = not at all, 1 = a little bit, 2 = somewhat, 3 = quite a bit and 4 = very much.

The BCS is composed of ten items targeting in Quality of Life in breast cancer but not already mentioned in the FACT-G. When the BCS is accompanying to the FACT-G, a new the 37-item is created known as the FACT-Breast (FACT-B).

Brief Symptom Inventory (BSI)

The BSI measures current psychological distress. This survey instrument consists of 53 items, expressing a feeling or thought, and is scored on a 5-point scale: 0 (no such problem) to 4 (severe problem). The score reflects 9 dimensions including somatization, obsessive-compulsive, interpersonal sensitivity, depression, anxiety, hostility, psychoticism, phobic anxiety, and paranoid ideation. Scores are represented by a distribution of 0–100, with high scores denoting greater psychological distress.

Sexual Activity Questionnaire (SAQ)

The SAQ assesses sexual behavior, quantifies the effects of cancer treatments on sexuality in the individual and it is consisted of three subcategories; pleasure (desire, enjoyment, and satisfaction), discomfort (dryness and pain), and habit (how usual the reported behavior is). Pleasure scores range from 0 to 18. Discomfort scores range from 0 to 6. Higher score shows lower discomfort and higher pleasure respectively [15].

Impact of Event Scale (IES)

A brief, easily answered self-report questionnaire consisting of 22 questions, not diagnostic for Post Traumatic Stress Disorder, is an instrument to assess the subjective response to a specific stressful event. It measures the frequency of disturbing and avoidant issues. The scale consists of 15 items (7 intrusion items and 8 avoidance items) [16,17].

Mishel Uncertainty in illness (MUIS)

The MUIS assesses complexity in accepting the meaning of illness-related events, consisting by four subscales that measure the patients' perceptions of the inconsistency, indistinctness and complexity of information given them. It has high internal reliability and

convergent validity [18]. Higher MUIS scores equal greater uncertainty.

Profile of Mood States (POMS)

POMS is a standard validated psychological test formulated by McNair et al. [19]. The questionnaire contains 65 words/statements that describe feelings of patients. The test requires patients to indicate for each expression or statement how they have been feeling in the past week.

Michigan Breast Reconstruction Outcome Study satisfaction (MBROS-S)

This questionnaire comprises 7 items divided into two scales. Five items assess the patient's generic satisfaction and 2 items measure satisfaction with the cosmetic result [20].

MBROS-Body Image questionnaire (MBROS-BI)

This was the second questionnaire developed by the MBROS team [21]. It consists 9 items on one scale. It was designed to measure the patient's perception of her physical image after breast surgery. It manages to calculate a body image score (BI score).

Short Form Health Survey (SF-36)

The SF-36 is a generic, short-form health survey with 36 self reported items. It consists of an 8-scale profile including functional health, well-being scores, psychological, physical and mental health summary measures and a health utility index. Accordingly, the SF-36 is useful in researches of general and specific populations, comparing the relative saddle of diseases and in discovering the health benefits produced by the variety of different treatments [22-25].

Body Image after Breast Cancer Questionnaire (BIBQ)

The BIBCQ is a survey instrument with 45 common items, 6 items for women with two breasts, and 2 items specific to women without one or both breasts. There are six scales, reflecting six domains of body image: vulnerability, body stigma, limitations, body concerns, transparency and arm concerns. The BIBCQ was created to measure body image in a wide-ranging and significant fashion, empowering useful measurements and comparisons. The subscales enable the flexible use of this questionnaire according to the needs of the research [25].

Breast impact of treatment scale (BITS)

This instrument assesses the body image in clinical oncology, conceptualizing the surgical therapy for breast cancer as a potential traumatic stress generator on a female's body image. BITS assess the body image distress as disturbing thoughts and avoidant behaviors are appearing. Intrusive items estimate insidious thoughts as "things I see or hear remind me that my body is different". Avoidant items measure limited cognitive experience, subjective knowledge of feelings, as "I feel self conscious about letting my partner see my scar" [26].

Body satisfaction scale (BSS)

BSS measures the subjective aspect of postoperative external body satisfaction with appearance and the weight [27]. BSS items are processed in a 5 point satisfaction/dissatisfaction scale with a lower score reflecting greater body satisfaction and a higher score reflecting greater body dissatisfaction.

Cancer Rehabilitation Evaluation System (CARES)

The CARES is a very detailed survey instrument assessing cancer patient's issues and needs. Its validity and reliability have been extensively proven [28,29]. The CARES scores are global and it includes five higher order factors referred to as summary scales and 31 more specific subscales. The domains assessed by five higher order summary scales are the following: physical, psychosocial, medical and sexual [30]

Rosenberg-EPM Self-Esteem Scale

The scale comprises 10 questions, with four answers possible: strongly agree, agree, disagree, or strongly disagree. The score of the scale ranges from 0 (best possible self-esteem) to 30 (worst possible self-esteem) [31].

State-Trait Anxiety Inventory (STAI)

The State-Trait Anxiety Inventory (STAI) 34 is a self-report measure that estimates a patients current level of anxiety. The internal consistency reliability is very good and it has been widely used in clinical and medical populations [32,33].

Center for Epidemiologic Studies-Depression tool (CES-D)

This is a reliable 20-item self-report instrument measuring depression. Its focus on the affective elements

of depression rather than the physic symptoms makes it useful in medical populations. It has shown high consistency in both general and patient populations [34,35].

Multidimensional Body-Self-Relations Questionnaire—Appearance Evaluation (MBSRQ)

It assesses the degree of generic satisfaction with its body and physical appearance. It consists of seven 5-point items (disagree-agree) and high scores on the MBSRQ reflect favorable evaluations of overall appearance [36].

Body Image Visual Analogue Scale

It is a three item based scale that assesses total body satisfaction, fulfillment with chest area, and satisfaction with abdominal area. Participants rate items on a 1-to-10 scale, reflecting complete dissatisfaction to complete satisfaction [37].

Psychiatric Symptom Index (PSI)

The PSI is a quantitative measure of the severity of emotional distress during the 7 days prior to the interview. It is based on a 4-point scale grading from “never” to “very often.” It’s ranges from 0 (no symptoms) to 100 (all symptoms at maximum intensity) [38].

The Locke-Wallace Marital Adjustment Test (LWMAT)

This instrument is used to measure marital satisfaction. LWMAT scores ranging from 2 to 158, with higher scores reflecting higher satisfaction [39,40].

Breast-Q

Andrea Pusic, MD, of Memorial Sloan-Kettering Institute for Cancer Research, create a new patient-reported outcome measure collecting and processing data about the impact and effectiveness of breast surgery. The BREAST-Q has with scales that evaluate both satisfaction and quality of life. It is evaluated and the results show high reliability, validity and approval to surgical intervention across all scales [41-43].

Author - Year	Manuscript Title	Health Related Quality of Life instruments
Mogens Groenvold - 2009 (44)	Health-related quality of life in early breast cancer	EORTC-C30 , HADS
A.E. Isern et al - 2007 (45)	Aesthetic outcome, patient satisfaction, and health-related quality of life in women at high risk undergoing prophylactic mastectomy and immediate breast reconstruction	SF-36 , HADS
E. De Gournay et al - 2010 (46)	Evaluation of quality of life after breast reconstruction using an autologous latissimus dorsi myocutaneous flap	MBROS-S, MBROS-BI, EORTC QLQ-C30, EORTC QLQ-BR23
Jing Han et al - 2009 (47)	Quality of life and satisfaction after breast cancer operation	EORTC QLQ-C30, EORTC QLQ-BR23
Mary J. Nissen et al - 2000 (48)	Quality of Life after Breast Carcinoma Surgery	MUIS,POMS,FACT-B
D.F. Veiga - 2004 (49)	Quality of life outcomes after pedicle TRAM flap delayed breast reconstruction	SF-36
H.M. Heneghan et al - 2011 (50)	Quality of life after immediate breast reconstruction and skin-sparing mastectomy. A comparison with patients undergoing breast conserving surgery.	EORTC QLQ-C30, EORTC QLQ-BR23, FACT-B
Yvonne Brandberg et al - 2008 (51)	Psychological Reactions, Quality of Life, and Body Image after Bilateral Prophylactic Mastectomy in Women At High Risk for Breast Cancer: A Prospective 1-Year Follow-Up Study	SAQ, BIS, HADS, SF-36
Medina Franco H. et al - 2010(52)	Body image perception and quality of life in patients who underwent breast surgery.	BIS, SF-36

Ali Montazeri - 2008 (53)	Health-related quality of life in breast cancer patients: A bibliographic review of the literature from 1974 to 2007	EORTC QLQ-C30, EORTC QLQ-BR23, FACT-B
Anne F Klassen et al - 2009 (54)	Satisfaction and quality of life in women who undergo breast surgery: A qualitative study	BREAST-Q
John A. Giroto et al - 2003 (55)	Breast Reconstruction in the Elderly: Preserving Excellent Quality of Life	SF-36
Edwin G. Wilkins et al - 2000 (21)	Prospective Analysis of Psychosocial Outcomes in Breast Reconstruction: One-Year Postoperative Results from the Michigan Breast Reconstruction Outcome Study	SF-36, FACT-B
Toni Zhong et al - 2011 (56)	Patient Satisfaction and Health-Related Quality of Life after Autologous Tissue Breast Reconstruction	BREAST-Q, HADS, IES
Constance M. Chen et al - 2010 (57)	Measuring Quality of Life in Oncologic Breast Surgery: A Systematic Review of Patient-Reported Outcome Measures	EORTC QLQ BR-23, FACT-B, BIS, BIBCQ, BREAST-Q
Rosson GD et al - 2013 (58)	Quality of life before reconstructive breast surgery: FA preoperative comparison of patients with immediate, delayed, and major revision reconstruction	BREAST-Q
Adel Denewer et al - 2011 (59)	Quality of life among Egyptian women with breast cancer after sparing mastectomy and immediate autologous breast reconstruction: a comparative study	BITS, BSS
Gerald P. H. Gui et al - 2003 (60)	Immediate breast reconstruction using bio dimensional anatomical permanent expander implants: a prospective analysis of outcome and patient satisfaction.	EORTC QLQ BR-23
Paula L. Kraus - 1999 (61)	Body image, decision making, and breast cancer treatment	BIS
Kojiro Shimozuma et al - 1999 (62)	Quality of life in the first year after breast cancer surgery: rehabilitation needs and patterns of recovery	CARES
Yvonne Brandberg et al - 1999 (63)	A prospective randomized study (named SVEA) of three methods of delayed breast reconstruction. Study design, patients' preoperative problems and expectations	SF-36,
Avis, Nancy E et al - 2005 (64)	Quality of Life among Younger Women With Breast Cancer	FACT-B
By Patricia A. Ganz et al - 2003 (65)	Breast Cancer in Older Women: Quality of Life and Psychosocial Adjustment in the 15 Months After Diagnosis	SF-36, CARES-SF
Z.-Y. He et al - 2012 (66)	A comparison of quality of life and satisfaction of women with early-stage breast cancer treated with breast conserving therapy vs. mastectomy in southern China	FACT-B
Volker Arndt et al - 2008 (67)	Quality of life over 5 years in women with breast cancer after breast-conserving therapy versus mastectomy: a population-based study	EORTC QLQ-C30, EORTC QLQ BR-23
Chang JT et al - 2007 (68)	Health-related quality of life and patient satisfaction after treatment for breast cancer in northern Taiwan	FACT-B
Daniela F. Veiga et al - 2010 (69)	Quality-of-life and self-esteem outcomes after onco-plastic breast-conserving surgery	SF-36, the Rosenberg-EPM Self-Esteem Scale
Patricia A. Parker et al - 2007 (70)	Short-term and long-term psychosocial adjustment and quality of life in women undergoing different surgical procedures for breast cancer	CES-D, STAI, MBSRQ, Body Image Visual Analogue Scale, SAQ, SF-36

Mary J. Nissen et al - 2000 (71)	Quality of Life after Breast Carcinoma Surgery: A Comparison of Three Surgical Procedures	MUIS, POMS, FACT-B
Michel Dorval et al - 1998 (72)	Type of mastectomy and quality of life for long term breast carcinoma survivors	PSI, LWMAT
Randy S. Roth et al - 2005 (73)	Quality of life and affective distress in women seeking immediate versus delayed breast reconstruction after mastectomy for breast cancer	SF-36, FACT-B

Table 1: Manuscripts reviewed.

Short Name	Abbreviation
EORTC QLQ -C30	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core (30 items)
EORTC QLQ -BR23	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire for Breast Cancer (23 items)
HADS	Hospital Anxiety and Depression Scale; BIS: Body Image Scale
FACT-B	Functional Assessment of Breast Cancer Therapy
SF-36	Short Form Health Survey (36 items)
PF-10	Physical Functional Subscale (10 items)
CARES-SF	Cancer Rehabilitation Evaluation System – Short Form
CARES	Cancer Rehabilitation Evaluation System; PSI: Psychiatric Symptom Index
LWMAT	Locke-Wallace Marital Adjustment Test
MUIS	Mishel Uncertainty in Illness Scale
POMS	Profile of Mood States
BSS	Body satisfaction scale
SAQ	Sexual Activity Questionnaire
MBROS-S	Michigan Breast Reconstruction Outcome Study satisfaction
MBROS-BI	MBROS-Body Image questionnaire
BITS	Breast impact of treatment scale
BSS	Body Satisfaction Scale
CARES	cancer rehabilitation evaluation system
STAI	State-Trait Anxiety Inventory
CES-D	Center for Epidemiologic Studies-Depression tool
LWMAT	The Locke-Wallace Marital Adjustment Test

Table 2: Questionnaire Abbreviations.

Results

Overall, 24 different survey instruments were identified within the 31 included studies (Diagram 1).

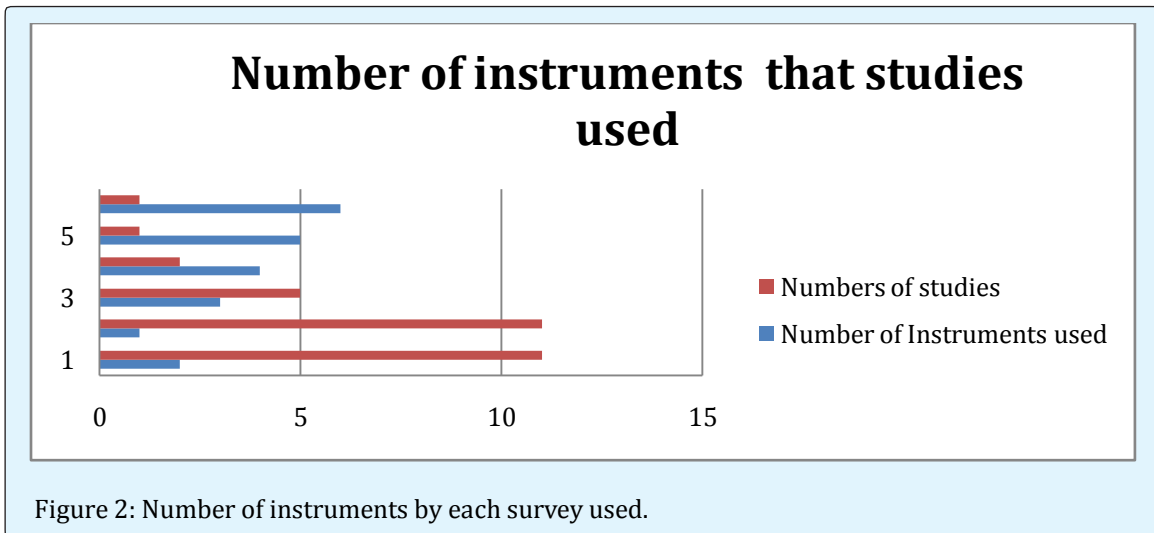
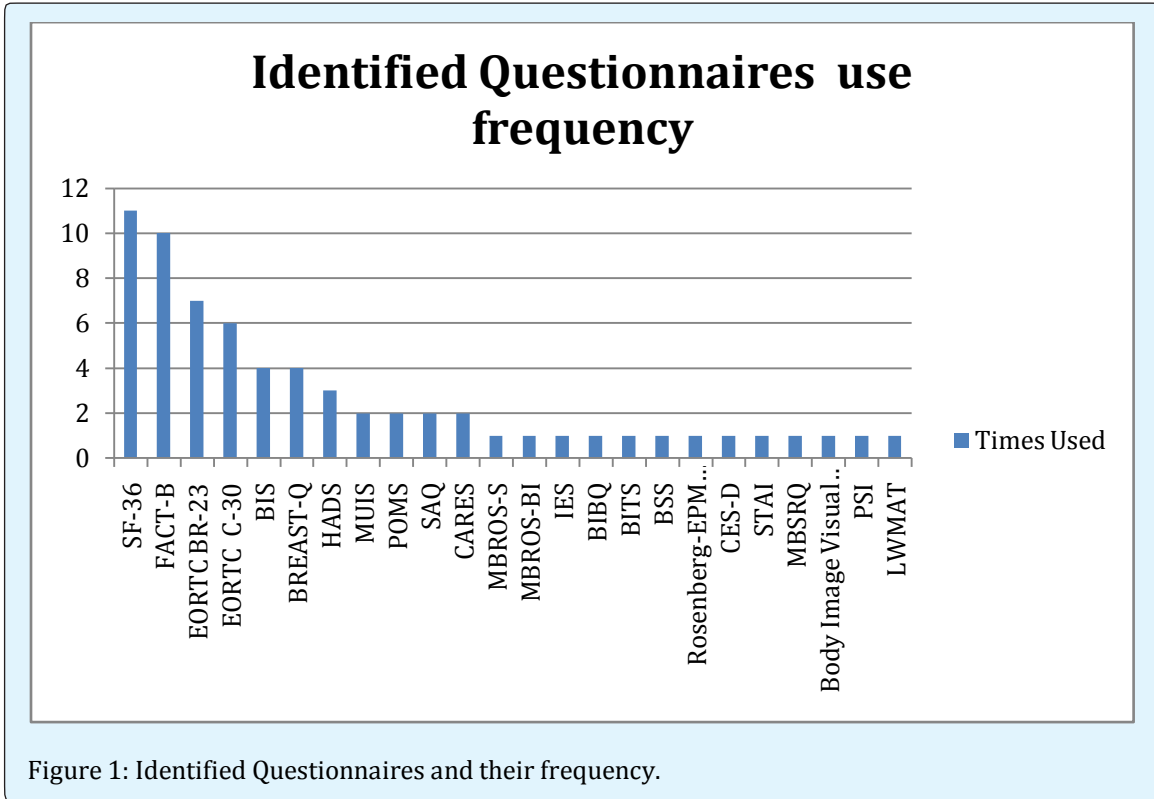
The most frequently used questionnaire is SF-36 and then FACT-B.

Most studies used more than 1 questionnaire (Diagram 2).

All those questionnaires could be separated in general about cancer and specific about breast cancer and outcome after mastectomy with or without reconstruction.

In those 31 studies a total of 66 questionnaires were used. 41 of those survey instruments were generic and

the other 25 focused on specific breast issues (Diagram 3).



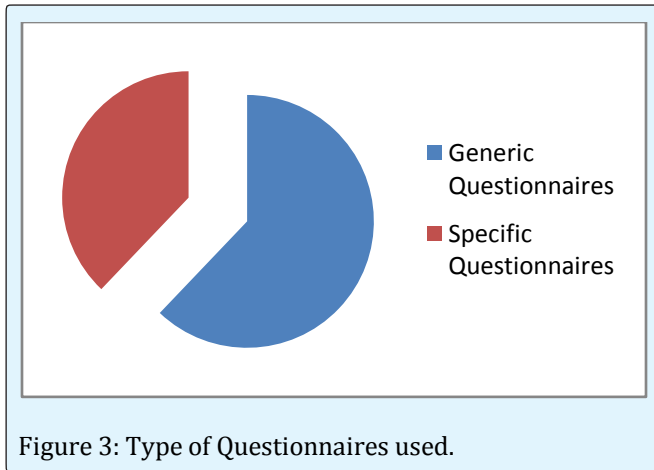


Figure 3: Type of Questionnaires used.

Discussion

Items measured in quality of life questionnaires vary to their focus degree on particular aspects of patients' activities and functions and conditions. There are measures focusing on particular activities of daily living, while others assess physical conditions, other health related factors such as symptoms, emotional conditions, cognition, discernment of health etc (4).

The advantages offered in research by measuring specific items are the greater knowledge for physicians, more acute focus on areas of particular concern, and may promote better responsiveness to disease-targeting interventions. However general measured items promote comparisons across interference and diagnostic cases, which is particularly important for creating guidelines. They also allow inspect multiple disease conditions achieving dysfunctions to be identified (74,75). Quality of life all is affected by all the diseases and disabilities and all the effort of the Quality of Life measurement is not only to collect clinical data significant to the disease, but to reveal the effects of the disease on general function. Thus, general items seem to be more suitable as they can examine a wider range of dysfunctions, that may concern different systems (76) e.g. sexual and psychological disorders of women who underwent mastectomy.

According to our experience and in the handle of assessing Quality of Life of women who underwent mastectomy with or without following reconstruction, considering the wide effects of this surgical procedure and multidimensional appeal of the woman patient it is more ideal to use more than one instrument in the research. The main disadvantage of using all this amount of survey instruments is that patient may be bored and not so energetic to participate to the research. The combination of both generic and specific questionnaires in measuring health related quality of life of breast cancer

patients is the best method. The combination of the results of those questionnaires can guarantee reliability and validity of the research.

One of the biggest issues in HQL evaluation is the quality assurance. The lack of quality in a medical research can dissipate all the efforts of achieving sufficient population orientation, statistical analysis and results. Quality-control projects are successful if they approximate existing quality-control mechanisms in the trial group. Nevertheless, it is wise to use more quality-control mechanisms. The management of a HQL research is better to be organized by one person, who has the primary role and responsibility of checking periodically the quality guidelines and handling the collected data.

Conclusions

The use of both generic, like SF-36, EORTC QLQ Q30, and breast cancer specific questionnaires, like EORTC QLQ BR23 and Brest-Q is best approach to the study of health related quality of life of breast cancer patients. The researchers should keep in mind that a large number of questionnaires is not easily answered by patients.

When the researchers use more than one questionnaire some of the questions are repeated. With great precaution the researcher could avoid the repeat of same questions in order to help the patient to quicker answer all the scaled requested.

In order to search the truth about the consequences in patient's life after the dramatic effect of breast cancer and mastectomy, researchers should approach the women with care. The most correct communication will emerge the best contact result and by this way the patients trust the researchers and speak honestly about their real feelings and thoughts in relation to their new life reality and activities.

References

1. Donovan K, Sanson-Fisher RW, Redman S (1989) Measuring quality of life in cancer patients. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 7(7): 959-968.
2. Campbell RJ (1976) Collaboration for quality; as seen by the manufacturer. *Supervisor nurse* 7(11): 51-52.
3. Goodinson SM, Singleton J (1989) Quality of life: a critical review of current concepts, measures and their clinical implications. *Int j nurs stud* 26(4): 327-341.

4. Bergner M (1989) Quality of life, health status, and clinical research. *Medical care* 27(S3): S148-S156.
5. Revicki DA (1989) Health-related quality of life in the evaluation of medical therapy for chronic illness. *The Journal of family practice* 29(4): 377-380.
6. Parkin DM, Bray F, Ferlay J, Pisani P (2005) Global cancer statistics, 2002. *CA: a cancer journal for clinicians* 55(2): 74-108.
7. Albo D, Wayne JD, Hunt KK, Rahlfs TF, Singletary SE, et al. (2001) Anaphylactic reactions to isosulfan blue dye during sentinel lymph node biopsy for breast cancer. *American journal of surgery* 182(4): 393-398.
8. Webster DJ, Mansel RE, Hughes LE (1984) Immediate reconstruction of the breast after mastectomy. Is it safe? *Cancer* 53(6): 1416-1419.
9. Wellisch DK, Schain WS, Noone RB, Little JW (1985) Psychosocial correlates of immediate versus delayed reconstruction of the breast. *Plastic and reconstructive surgery* 76(5): 713-718.
10. Hopwood P, Fletcher I, Lee A, Al Ghazal S (2001) A body image scale for use with cancer patients. *European journal of cancer* 37(2): 189-197.
11. Zigmond AS, Snaith RP (1983) The hospital anxiety and depression scale. *Acta psychiatrica Scandinavica* 67(6): 361-370.
12. Bjelland I, Dahl AA, Haug TT, Neckelmann D (2002) The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *Journal of psychosomatic research* 52(2): 69-77.
13. Brady MJ, Cella DF, Mo F, Bonomi AE, Tulskey DS, et al. (1997) Reliability and validity of the Functional Assessment of Cancer Therapy-Breast quality-of-life instrument. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 15(3): 974-986.
14. Cella DF, Tulskey DS, Gray G, Sarafian B, Linn E, et al. (1993) The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 11(3): 570-579.
15. Thirlaway K, Fallowfield L, Cuzick J (1996) The Sexual Activity Questionnaire: a measure of women's sexual functioning. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 5(1): 81-90.
16. Horowitz M, Wilner N, Alvarez W (1979) Impact of Event Scale: a measure of subjective stress. *Psychosomatic medicine* 41(3): 209-218.
17. Christianson S, Marren J (2012) The Impact of Event Scale - Revised (IES-R). *Medsurg nursing : official journal of the Academy of Medical-Surgical Nurses* 21(5): 321-322.
18. Mishel MH (1981) The measurement of uncertainty in illness. *Nursing research* 30(5): 258-263.
19. McNair DM (1984) Citation Classic - Manual for the Profile of Mood States. *Cc/Soc Behav Sci* 27.
20. Alderman AK, Kuhn LE, Lowery JC, Wilkins EG (2007) Does patient satisfaction with breast reconstruction change over time? Two-year results of the Michigan Breast Reconstruction Outcomes Study. *Journal of the American College of Surgeons* 204(1): 7-12.
21. Wilkins EG, Cederna PS, Lowery JC, Davis JA, Kim HM, et al. (2000) Prospective analysis of psychosocial outcomes in breast reconstruction: one-year postoperative results from the Michigan Breast Reconstruction Outcome Study. *Plastic and reconstructive surgery* 106(5): 1014-1025.
22. Ware JE, Sherbourne CD (1992) The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical care* 30(6): 473-483.
23. McHorney CA, Ware JE, Raczek AE (1993) The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Medical care* 31(3): 247-263.
24. Kempen GI (1992) The MOS Short-Form General Health Survey: single item vs multiple measures of health-related quality of life: some nuances. *Psychological reports* 70(2): 608-610.
25. Baxter NN, Goodwin PJ, McLeod RS, Dion R, Devins G, et al. (2006) Reliability and validity of the body image after breast cancer questionnaire. *The breast journal* 12(3): 221-232.

26. Frierson GM, Thiel DL, Andersen BL (2006) Body change stress for women with breast cancer: the Breast-Impact of Treatment Scale. *Annals of behavioral medicine : a publication of the Society of Behavioral Medicine* 32(1): 77-81.
27. Andersen BL, Legrand J (1991) Body Image for Women: Conceptualization, Assessment, and a Test of its Importance to Sexual Dysfunction and Medical Illness. *Journal of sex research.* 28(3): 457-477.
28. Vinokur AD, Threatt BA, Vinokur-Kaplan D, Satariano WA (1990) The process of recovery from breast cancer for younger and older patients. Changes during the first year. *Cancer.* 65(5): 1242-1254.
29. Schag CA, Heinrich RL, Aadland RL, Ganz PA (1990) Assessing problems of cancer patients: psychometric properties of the cancer inventory of problem situations. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association* 9(1): 83-102.
30. Ganz PA, Polinsky ML, Cohen M, Sacher J, Rofessart J (1986) Comprehensive Evaluation of the Rehabilitation Needs of Newly-Diagnosed Breast-Cancer Patients. *Breast cancer research and treatment* 8(1): 101.
31. Martin-Albo J, Nuniez JL, Navarro JG, Grijalvo F (2007) The Rosenberg Self-Esteem Scale: translation and validation in university students. *The Spanish journal of psychology* 10(2): 458-467.
32. Shedletsky R, Endler NS (1974) Anxiety: the state-trait model and the interaction model. *Journal of personality* 42(4): 511-527.
33. Kendall PC, Finch AJ, Auerbach SM, Hooke JF, Mikulka PJ (1976) The State-Trait Anxiety Inventory: a systematic evaluation. *Journal of consulting and clinical psychology* 44(3): 406-412.
34. Clark VA, Aneshensel CS, Frerichs RR, Morgan TM (1981) Analysis of Effects of Sex and Age in Response to Items on the Ces-D Scale. *Psychiatry research* 5(2): 171-181.
35. Roberts RE (1980) Reliability of the CES-D Scale in different ethnic contexts. *Psychiatry research* 2(2): 125-134.
36. Brown TA, Cash TF, Mikulka PJ (1990) Attitudinal Body-Image Assessment - Factor-Analysis of the Body-Self Relations Questionnaire. *J Pers Assess* 55(1-2): 135-144.
37. Mock V (1993) Body image in women treated for breast cancer. *Nursing research* 42(3): 153-157.
38. Ilfeld FW (1976) Further Validation of a Psychiatric Symptom Index in a Normal Population. *Psychological reports* 39(3): 1215-1228.
39. Dorval M, Maunsell E, Deschenes L, Brisson J, Masse B (1998) Long-term quality of life after breast cancer: Comparison of 8-year survivors with population controls. *Journal of Clinical Oncology* 16(2): 487-494.
40. Locke HJ, Wallace KM (1959) Short Marital-Adjustment and Prediction Tests - Their Reliability and Validity. *Marriage Fam Living* 21(3): 251-255.
41. Pusic AL, Klassen AF, Scott AM, Klok JA, Cordeiro PG, et al. (2009) Development of a new patient-reported outcome measure for breast surgery: the BREAST-Q. *Plastic and reconstructive surgery* 124(2): 345-353.
42. Pusic AL, Klassen AF, Cano SJ (2012) Use of the BREAST-Q in clinical outcomes research. *Plastic and reconstructive surgery* 129(1): 166e-167e.
43. Pusic AL, Klassen AF, Cano SJ (2012) Discussion: The BREAST-Q: further validation in independent clinical trials. *Plastic and reconstructive surgery* 130(3): 482e-483e.
44. Groenvold M (2010) Health-related quality of life in early breast cancer. *Danish medical bulletin* 57(9): B4184.
45. Isern AE, Tengrup I, Loman N, Olsson H, Ringberg A (2008) Aesthetic outcome, patient satisfaction, and health-related quality of life in women at high risk undergoing prophylactic mastectomy and immediate breast reconstruction. *Journal of plastic, reconstructive & aesthetic surgery : JPRAS* 61(10): 1177-1187.
46. De Gournay E, Bonnetain F, Tixier H, Loustalot C, Dabakuyo S, et al. (2010) Evaluation of quality of life after breast reconstruction using an autologous latissimus dorsi myocutaneous flap. *European journal of surgical oncology : the journal of the European*

- Society of Surgical Oncology and the British Association of Surgical Oncology 36(6): 520-527.
47. Han J, Grothuesmann D, Neises M, Hille U, Hillemanns P (2010) Quality of life and satisfaction after breast cancer operation. *Archives of gynecology and obstetrics* 282(1): 75-82.
 48. Nissen MJ, Lazovich D, Jolitz G (2000) Breast carcinoma after cancer at another site: method of detection, tumor characteristics, and surgical treatment. *Cancer* 89(9): 1999-2005.
 49. Veiga DF, Sabino Neto M, Ferreira LM, Garcia EB, Veiga Filho J, et al. (2004) Quality of life outcomes after pedicled TRAM flap delayed breast reconstruction. *British journal of plastic surgery* 57(3): 252-257.
 50. Heneghan HM, Prichard RS, Lyons R, Regan PJ, Kelly JL, et al. (2011) Quality of life after immediate breast reconstruction and skin-sparing mastectomy - a comparison with patients undergoing breast conserving surgery. *European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology.* 37(11): 937-943.
 51. Brandberg Y, Sandelin K, Erikson S, Jurell G, Liljegren A, et al. (2008) Psychological reactions, quality of life, and body image after bilateral prophylactic mastectomy in women at high risk for breast cancer: a prospective 1-year follow-up study. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 26(24): 3943-3949.
 52. Medina-Franco H, Garcia-Alvarez MN, Rojas-Garcia P, Trabanino C, Drucker-Zertuche M (2010) Body image perception and quality of life in patients who underwent breast surgery. *The American surgeon* 76(9): 1000-1005.
 53. Montazeri A (2008) Health-related quality of life in breast cancer patients: a bibliographic review of the literature from 1974 to 2007. *Journal of experimental & clinical cancer research : CR* 27(1): 32.
 54. Klassen AF, Pusic AL, Scott A, Klok J, Cano SJ (2009) Satisfaction and quality of life in women who undergo breast surgery: a qualitative study. *BMC women's health* 9:11.
 55. Girotto JA, Schreiber J, Nahabedian MY (2003) Breast reconstruction in the elderly: preserving excellent quality of life. *Annals of plastic surgery* 50(6): 572-578.
 56. Zhong T, McCarthy C, Min S, Zhang J, Beber B, et al. (2012) Patient satisfaction and health-related quality of life after autologous tissue breast reconstruction: a prospective analysis of early postoperative outcomes. *Cancer* 118(6): 1701-1709.
 57. Chen CM, Cano SJ, Klassen AF, King T, McCarthy C, et al. (2010) Measuring quality of life in oncologic breast surgery: a systematic review of patient-reported outcome measures. *The breast journal* 16(6): 587-597.
 58. Rosson GD, Shridharani SM, Magarakis M, Manahan MA, Basdag B, et al. (2013) Quality of life before reconstructive breast surgery: FA preoperative comparison of patients with immediate, delayed, and major revision reconstruction. *Microsurgery* 33(4): 253-258.
 59. Denewer A, Farouk O, Kotb S, Setit A, Abd El-Khalek S, et al. (2012) Quality of life among Egyptian women with breast cancer after sparing mastectomy and immediate autologous breast reconstruction: a comparative study. *Breast cancer research and treatment* 133(2):537-544.
 60. Gui GP, Tan SM, Faliakou EC, Choy C, A'Hern R, et al. (2003) Immediate breast reconstruction using biodimensional anatomical permanent expander implants: a prospective analysis of outcome and patient satisfaction. *Plastic and reconstructive surgery* 111(1): 125-138.
 61. Kraus PL (1999) Body image, decision making, and breast cancer treatment. *Cancer nursing* 22(6): 421-427.
 62. Shimozuma K, Ganz PA, Petersen L, Hirji K (1999) Quality of life in the first year after breast cancer surgery: rehabilitation needs and patterns of recovery. *Breast cancer research and treatment* 56(1): 45-57.
 63. Brandberg Y, Malm M, Rutqvist LE, Jonsson E, Blomqvist L (1999) A prospective randomised study (named SVEA) of three methods of delayed breast reconstruction. Study design, patients' preoperative problems and expectations. *Scandinavian journal of*

- plastic and reconstructive surgery and hand surgery / Nordisk plastikkirurgisk forening [and] Nordisk klubb for handkirurgi 33(2): 209-216.
64. Avis NE, Crawford S, Manuel J (2005) Quality of life among younger women with breast cancer. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 23(15): 3322-3330.
 65. Ganz PA, Guadagnoli E, Landrum MB, Lash TL, Rakowski W, et al. (2003) Breast cancer in older women: quality of life and psychosocial adjustment in the 15 months after diagnosis. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 21(21): 4027-4033.
 66. He ZY, Tong Q, Wu SG, Li FY, Lin HX, et al. (2012) A comparison of quality of life of early breast cancer patients treated with accelerated partial breast irradiation versus whole breast irradiation in China. *Breast cancer research and treatment* 133(2): 545-552.
 67. Arndt V, Stegmaier C, Ziegler H, Brenner H (2008) Quality of life over 5 years in women with breast cancer after breast-conserving therapy versus mastectomy: a population-based study. *Journal of cancer research and clinical oncology* 134(12): 1311-1318.
 68. Chang JT, Chen CJ, Lin YC, Chen YC, Lin CY, et al. (2007) Health-related quality of life and patient satisfaction after treatment for breast cancer in northern Taiwan. *International journal of radiation oncology, biology, physics* 69(1): 49-53.
 69. Veiga DF, Veiga-Filho J, Ribeiro LM, Archangelo I, Balbino PF, et al. (2010) Quality-of-life and self-esteem outcomes after oncoplastic breast-conserving surgery. *Plastic and reconstructive surgery* 125(3): 811-817.
 70. Parker PA, Youssef A, Walker S, Basen-Engquist K, Cohen L, et al. (2007) Short-term and long-term psychosocial adjustment and quality of life in women undergoing different surgical procedures for breast cancer. *Annals of surgical oncology* 14(11): 3078-3089.
 71. Nissen MJ, Swenson KK, Ritz LJ, Farrell JB, Sladek ML, et al. (2001) Quality of life after breast carcinoma surgery: a comparison of three surgical procedures. *Cancer* 91(7): 1238-1246.
 72. Dorval M, Maunsell E, Deschenes L, Brisson J (1998) Type of mastectomy and quality of life for long term breast carcinoma survivors. *Cancer* 83(10): 2130-2138.
 73. Roth RS, Lowery JC, Davis J, Wilkins EG (2005) Quality of life and affective distress in women seeking immediate versus delayed breast reconstruction after mastectomy for breast cancer. *Plastic and reconstructive surgery* 116(4): 993-1002.
 74. Bombardier C, Ware J, Russell IJ, Larson M, Chalmers A, et al. (1986) Auranofin therapy and quality of life in patients with rheumatoid arthritis. Results of a multicenter trial. *The American journal of medicine* 81(4): 565-578.
 75. Temkin NR, Dikmen S, Machamer J, McLean A (1989) General versus disease-specific measures. Further work on the Sickness Impact Profile for head injury. *Medical care* 27(S3): S44-S53.
 76. Kaplan RM, Anderson JP, Wu AW, Mathews WC, Kozin F, et al. (1989) The Quality of Well-being Scale. Applications in AIDS, cystic fibrosis, and arthritis. *Medical care* 27(S3): S27-S43.