Author's response to reviews

Title: Quality of life of Lithuanian women with early stage breast cancer

Authors:

  Giedre Bulotiene (giebul@yahoo.com)
  Jonas Veseliunas (redam@loc.lt)
  Valerijus Ostapenko (kruties.chirurgija@loc.lt)

Version: 3 Date: 20 December 2006

Author's response to reviews: see over
20 December 2006  
Dr Lolu da-Silva
Assistant Editor
BMC-series Journals
BioMed Central
Re: MS: 1995616612104954 (BioMed Central Public Health)
Quality of life of Lithuanian women with early stage breast cancer.

Dear Dr. Lolu da Silva:
My co-authors and I were pleased to receive the reviews of our manuscript. Please consider the attached revision, which incorporates the following changes in response to the reviews by Mr. Santosh K Chaturvedi and Dr. Evaon Wong-Kim:
Author's response to reviews
Title: Quality of life of Lithuanian women with early stage breast cancer
Authors:
Giedre Bulotiene – giebul@yahoo.com;
Jonas Veseliunas – jonas.veseliunas@loc.lt;
Valerijus Ostapenko – kruties.chirurgija@loc.lt
Version: 3  Date: xx December 2006
Reviewer 1 (Santosh K Chaturvedi)
--------------------------------------------------------------------------
Major Compulsory Revisions

Santosh K Chaturvedi: How many persons returned the assessment forms sent by mail ?
What was the drop out or attrition rate?

Response: In response to these questions, we have added the following sentences to the Materials and Methods:

117 patients with T1-T2/N0-N2/M0 stages of breast cancer were enrolled in the study… The answers were received from 77 (66%) patients. No respondents were contacted by phone to know the reasons. The most frequent explanation was: “because she felt bad” or “didn’t understand some questions”. Other reasons were: “at that time she was away” or “didn’t get a mail”. Only few trace because their address or phone number was changed. 77 patients who completed the questionnaires twice were included in the study.

Santosh K Chaturvedi: What was the statistical significance of the differences in the scores for each subscale and total?

Response: In response to this question, we have added a new table that includes p values:

Table 2. FACT scores that changed significantly over time.

And, we have added the following sentences to the Materials and Methods:

T-test for dependent samples was used to compare the mean score values for the QOL domains. Significance was set at p<0.05.

Santosh K Chaturvedi: Were there adverse reactions or toxicity due to chemotherapy?

Response: The adverse reactions noted above are reflected in seven items of Physical Well-Being subscale:

I have a lack of energy
I have nausea
Because of my physical condition, I have trouble meeting the needs of my family
I have pain
I am bothered by side effects of treatment
I feel ill
I am forced to spend time in bed

Our investigation didn’t found statistically significant differences in PWB scores one week after surgery and nine months after surgery. And, in response to this question, we have added the following sentence to the Discussion:

There weren’t found significant changes in patients’ physical well-being nine months after surgery.

Santosh K Chaturvedi: The possible reasons for changes in the quality of life, social and emotional well being in the pre and post scores need to be discussed. The authors could attempt multivariate statistics to identify predictors for poor QOL during follow up.

Response: In keeping with the spirit of this recommendation, we have expanded the analysis of changes in QOL and have analyzed the social and demographic factors’ (age, education, occupation and marital status) influence. We conducted a multivariate analysis. On multivariate regressive analysis patients’ marital status was found to significant influence the changes of FWB. Changes of QOL weren’t significantly influenced by other social and demographic variables including patients’ age, education and occupation.

We have made several changes:

We have added demographic characteristics of patients (education, occupation and marital status) to the Table 1:

Table 1: Clinical and demographic characteristics of patients.

We have added following sentences to the Results:

Multivariate regressive analysis showed the marital status to be a significant determinant in the changes of QOL functional well-being domain (Table 3). In the sample of married women SWB, FACT-An, Total FACT-G, Total FACT-An and TOI-Anemia scores decreased significantly nine months after the surgery (Figure 1). In the sample of not married women only the SWB and EWB scores decreased significantly over time.

We have added a table:

Table 3. Results of multivariate regressive analysis.

We have added a figure:

Figure 1. FACT scores that changed significantly over time for married (M) and not married (NM) patients.

We have added a paragraph to the Discussion:
One of the possible explanations for the QOL worsening in social domain in nine months after surgery was the changing role of the women in the family due to their illness or treatment. We also found that QOL was influenced by patients’ marital status more than other social and demographic variables including patients’ age, education and occupation. These results on QOL of Lithuanian women with early stage breast cancer differ from the findings of other researches (4, 5).

And, we have added the following sentence to the conclusion:

3. Marital status more than other social and demographic factors has influenced changes in the quality of life of Lithuanian women in nine months after surgery.

Minor Essential Revisions

Santosh K Chaturvedi: The authors should also discuss the limitations of the study.

Response: We have added the following paragraph to the Discussion:

Certain study limitations were that the differences between those who completed questionnaires nine months after surgery and those who did not might overestimate QOL scores. Besides, the first time patients answered the questionnaires at the hospital setting and the second time at home and this might influence their answers. A second limitation of this study was a small number of patients when divided into four groups: mastectomy with/without chemotherapy and BCT with/without chemotherapy. This might reduce the possibility to generalize these results.

Santosh K Chaturvedi: The Results & discussion sections should be separate.

Response: This correction has been made.

Santosh K Chaturvedi: The Tables 1 & 2 can be deleted and the information provided in the Result section. Only figures with statistically significant differences could be retained, and other figures omitted.

Response: Corrections made.

Reviewer 2 (Evaon Wong-Kim)

General
Evaon Wong-Kim: The abstract should be rewritten so that it can be more succinct.

Response: In response to this suggestion, the abstract was rewritten.
Background
Evaon Wong-Kim: On page 3, second sentence under second paragraph 2, it is unclear what Analysis of 27 scientific researches allowed concluding . . . Does this mean a meta-analysis was conducted or just a literature review?

Response: We meant "A literature review" and have made this correction:

A literature review (3) showed that the women’s psychological vulnerability and adaptation after mastectomy and breast conserving treatment (BCT)…

Evaon Wong-Kim: The authors jumped into BCT without defining what BCT includes in the Background section.

Response: This correction has been made.

Evaon Wong-Kim: On second paragraph, line 5 stated: “The study of 5 year . . .” what is the study? There is no reference after “the study.”

Response: Correction made:

The study (4) of 5 years duration…

Evaon Wong-Kim: Under paragraph 5 it is unclear what Functional Assessment of Cancer Anemia Subscale . . . it is unclear what this sentence means.

Response: Correction made:

The Anemia Subscale of the Functional Assessment of Cancer Therapy (FACT-An) is able to capture physical and psychological aspects of fatigue (7).

Materials and Methods
Evaon Wong-Kim: Due to the different types of subscales, even with the table to explain these measuring tools the first few paragraphs are still very confusing. The authors may want to consider rewriting this section and focus more on the instrument that was actually used to assess quality of life and what are the items included in this subscale.

Response: In response to this suggestion, this section was rewritten focusing on the instrument that was actually used:

The FACT – G is a 27-item compilation of general questions divided into four primary QOL domains: Physical well-being (PWB), Social/Family well-being (SWB), Emotional well-being (EWB) and Functional well-being (FWB). Each domain is comprised of six to seven questions scored by use of a Likert-type scale ranging from 0 (not at all) to 4 (very much). The Total FACT-G score is obtained by summing up four individual subscale scores (PWB, EWB, SWB and FWB). The FACT-An includes 13 items that attempt to identify the intensity of fatigue experienced during the 7 days before questionnaire administration plus seven additional items (20 total) pertaining to symptoms associated with anemic processes (7). The Total FACT-An score is a sum of
four subscales plus Anemia subscale. Trial Outcome Index (TOI) is a sum of PWB, FWB and Anemia subscales. The TOI is an efficient summary index of physical/functional outcomes. All scales are scored so that a higher score means better quality of life.

The Results and Discussion

**Evaon Wong-Kim:** This section needs major revision. There are several problems in this section. First of all it is unclear what the authors mean by “significance.” Does it mean statistical significant differences between the two groups? If so, then they need to support these differences or lack of differences by providing p values and explaining what kind of statistical test they performed, such as t tests or Chi Squares.

**Response:** In response to these questions, we have added a new table that includes p values:

Table 2. FACT scores that changed significantly over time.

And, we have added the following sentences to the Materials and Methods:

T-test for dependent samples was used to compare the mean score values for the QOL domains. Significance was set at p<0.05.

**Evaon Wong-Kim:** Also, is there enough statistical power to detect the differences if each group is further divided into with and without chemo, which will be a total of 4 groups?

**Response:** The statistical power might not be enough because of a small number of patients in each group (n=14, n=16, n=21 and n=26). In response to this question we have added a following sentence to the paragraph on the limitations of the study:

A second limitation of this study was a small number of patients when divided into four groups: mastectomy with/without chemotherapy and BCT with/without chemotherapy. This might reduce the possibility to generalize these results.

**Evaon Wong-Kim:** The authors may want to construct a table with the outcome variables provided with t scores and p values to indicate any statistical significant differences between or among the groups.

**Response:** In response to this suggestion, we have constructed a table provided with p values:

Table 2. FACT scores that changed significantly over time.

**Evaon Wong-Kim:** Besides reporting the outcomes of the study there is really no discussion included in this manuscript, what are some of the reasons the authors think may have contributed to the results of the study? Are women in Lithuanian women confronting different medical or social situations compared to other women to contribute to the results of this study? Because many of the published quality of life studies were conducted in the United States using white women it will be interesting to see how
Lithuanian women are confronting the same issues relating to sexuality and coping mechanism that may be different than women in the US.

Response: In keeping with the spirit of this recommendation, we have expanded the analysis of changes in QOL and have analyzed the social and demographic factors’ (age, education, occupation and marital status) influence. We conducted a multivariate analysis. Multivariate regressive analysis showed the marital status to be a significant determinant in the changes of FWB. Changes of QOL weren’t significantly influenced by other social and demographic variables including patients’ age, education and occupation.

We have made several changes:

We have added demographic characteristics of patients (education, occupation and marital status) to the Table 1:

Table 1: Clinical and demographic characteristics of patients.

We have added following sentences to the Results:

Multivariate regressive analysis showed the marital status to be a significant determinant in the changes of QOL functional well-being domain (Table 3). In the sample of married women SWB, FACT-An, Total FACT-G, Total FACT-An and TOI-Anemia scores decreased significantly nine months after the surgery (Figure 1). In the sample of not married women only the SWB and EWB scores decreased significantly over time.

We have added a table:

Table 3. Results of multivariate regressive analysis.

We have added a figure:

Figure 1. FACT scores that changed significantly over time for married (M) and not married (NM) patients.

We have added a paragraph to the Discussion:

One of the possible explanations for the QOL worsening in social domain in nine months after surgery was the changing role of the women in the family due to their illness or treatment. We also found that QOL was influenced by patients’ marital status more than other social and demographic variables including patients’ age, education and occupation. These results on QOL of Lithuanian women with early stage breast cancer differ from the findings of other researches (4, 5).

And, we have added the following sentence to the conclusion:
3. Marital status more than other social and demographic factors has influenced changes in the quality of life of Lithuanian women in nine months after surgery.

Thank you again for your interest in our manuscript. My coauthors and I look forward to hearing your final editorial decision.

Sincerely,

Giedre Bulotiene, MD
Institute of Oncology,
Vilnius University
Lithuania