Reviewer's report

Title: Health-related quality of life in survivors of stage I-II breast cancer: randomized trial of post-operative conventional radiotherapy and hypofractionated tomotherapy.

Version: 4 Date: 11 June 2012

Reviewer: Grit Welzel

Reviewer's report:

1. Is the question posed by the authors well defined?
   Yes.

2. Are the methods appropriate and well described?
   No. The authors used the mean score of all patients from both treatment arms as baseline score and then compared the changes from the baseline score at each time point with the two-sample t-test. From a statistical point of view it is an unusual approach. In this study with incomplete data, an analysis of covariance or a simple subtraction of the baseline score from the T1-T5 scores for each patient and then comparing the average changes using the two-sample t-test is the better statistical method (minor essential revision).

3. Are the data sound?
   No, not quite.
   The sample size drops from T3 to T5. Figures 2-5 indicate that the changes from baseline at T3, T4, and T5 were calculated from the mean score of all 121 patients at baseline. This approach is only acceptable if there are no differences between the baseline score of the n=121 patients and the baseline scores of the n=101/66/34 patients who were examined at T3/4/5.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
   Yes.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
   Yes.

6. Are limitations of the work clearly stated?
   Yes.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
   Yes.

8. Do the title and abstract accurately convey what has been found?
   Yes.
9. Is the writing acceptable?

Yes, but requires some revisions by the proofreaders or the authors. For example in the following phrases:

- “On the last day of radiotherapy, patients in both treatment arms had a decrease in global health status and functionings scores; an increase in fatigue (clinically meaningful increases in both arms), nausea and vomiting, and constipation; a decrease in arm symptoms; clinically meaningful increases in breast symptoms in CR patients and in systemic side effects in TT patients, and a slightly decrease in body image and future perspective.”

- “In November 2011, the 121 eligible patients had all been followed up for at least 3 months after the completion of radiotherapy.”

- “The Bonferroni correction was applied and the means scores were also tested with repeated measurement of ANOVA.”

- “Figures 2a–f show that that TT patients experienced greater long term improvements than CR patients in global health status and in all functioning scores except for social functioning, but these differences were not significant.”

- “At 3 years after the completion of radiotherapy, the breast symptom scores were increased in TT patients and continued to decrease in CR patients, but this difference between treatment arms not clinically meaningful (9.9 points, Table 5).” (minor essential revision).

**Level of interest:** An article of outstanding merit and interest in its field

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.