Author's response to reviews

Title: Two-year changes in quality of life in elderly patients with low-energy hip fractures. A case-control study

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Author's response to reviews: see over
Dear Editor,

Thank you for the comments and the positive attitude to our manuscript. We hereby submit the revised manuscript “Two-year changes in quality of life in elderly patients with low-energy hip fractures. A case-control study”

We have to the best of our abilities made changes in the manuscript according to the issues raised in the comments from the reviewer.

Yours sincerely

Gudrun Rohde,
RN, PhD
1. Reviewer's report

Reviewer: Inger Hallberg

Specific comments are:
- Major Compulsory Revisions
  1. The major limitation was the design of retrospective analyses of baseline HRQOL and GQOL and that the risk of recall bias is very high. The fracture patients are affected by the fracture when they report the pre-fracture data. It would be more interesting to follow the patients if HRQOL and GQOL data was also collected in connection with the fracture event. There is a need for a more extensive discussion regarding the choice of method design (advantages and disadvantages).

  Reply: The advantages and disadvantages of the design have been discussed further p. 17, Para. and p.18.

- Minor Essential Revisions
  2. Regarding the title: rephrase the title? A prospective case-control study to: A follow-up case-control study or A case-control study (since data results are both retrospective and prospective).

  Reply: The title has been rephrased.

  3. The authors use different concepts for the retrospective data, pre-fracture (in the fracture group) baseline and also inclusion. It would be advantageous to use the same concept or terms (i.e. recall data) in the manuscript.

  Reply: The terms pre-fracture and inclusion have been used through the manuscript

  4. In the statistical analyses: HRQOL (delta PSC and delta MCS) and GQOL (delta QOLS), what does ”delta” mean in this context?
5. How were subsequent fractures handled at the two-year follow up? Were there more new fractures in the patient group? Patient with hip fracture had increased risk of vertebral fracture and this fracture type could reduce HRQOL more than hip fracture. According to the manuscript, two years after baseline, the same differences (demographic and clinical characteristics) between groups were present except for anti-osteoporosis treatment. How many hip fracture patients used anti-osteoporosis treatment at the two-year follow up?

Reply: Unfortunately we were unable to measure subsequent vertebral fractures. The numbers of patients and controls using ART at the two-year follow-up have been added p.11, Para 2.

6. Missing data in HRQOL and GQOL questionnaires: It is not clear how many questionnaires were incomplete? Readers should have this information to assess the results in the study.

Reply: The numbers of questionnaire with one or more missing responses have been added, p.8, Para 2 and p.9, Para 2. Imputations for missing responses have been carried out in accordance with the guideline given by the developer of the questionnaires used in this study.

7. All data is presented as a group. Are there differences between women and men, which could affect the results of HRQOL and GQOL?

Reply: The numbers of men is small and statistically significant differences between women and men difficult to identify. We might argue that the results are more valid for women than for men, and that the inclusion of men would interrupt the results. However, when excluding the men from the analyses to assess the changes in HRQOL and GQOL over a period of two years within patients and controls the changes in HRQOL and GQOL persisted.

8. In the multiple linear regression analysis, independent variable age was used as five-year groups, why not as continuous data, i.e. the actual age?
Reply: The five-year groups were used based on comments given by reviewers in another manuscript of the same study-population, and clinical relevance.

- Discretionary Revisions

9. Data regarding the domains in SF-36 is usually presented in a particular order: physical function, role physical, bodily pain, general health, vitality, social function, role emotional and mental health. Presenting data in this order makes it easier to follow for the reader, in the article data is not presented in the same order in the different sections.

Reply: The order of the SF-36 domains have been presented in the order suggested by the reviewer

10. Information about height and weight gives more accurate information than only BMI in this population.

Reply: The information of current height and weight have been added in table 1.

11. Figure 2 is not very informative or easy to understand for the reader, it would be better with a table showing these data in order to increase the possibility to compare data between different studies. Figure 2 and 3 could be shown as a table instead.

Reply: We have chosen to keep the figures despite the suggestion given by the reviewer. We think that the figure illustrate the changes within the patients and controls over a two-year period better than a table.

12. Physical (PCS) and mental (MCS) component summary indexes were used in the study, but it was later concluded that the current PCS and MCS scoring procedure inaccurately summarizes subscale profile scores and should therefore be revised. Until then, component scores should be interpreted with caution and only in combination with profile scores. (ref: Taft C, Karlsson J & Sullivan M

Reply: We are aware of the discussion of the PCS and MCS summary scales pointed out by the reviewer. Both the eight SF-36 domains and the two summary scales are presented in the manuscript to illustrate the changes and differences in HRQOL.

13. Is there a need for references in the conclusion (19,20)? These references are also found at the end of the discussion.

Reply: We agree with the reviewer and the references have been removed.

2. Reviewer's report

Reviewer: Ian Cameron

Major Compulsory Revisions:
1. The case control methodology is not the preferred method of investigation of the topic. Ideally a cohort study should be used. The authors should discuss this.

Reply: The study-design has been discussed further on p. 17 and p 18.

2. Participants and controls in the study are younger and appear less disabled that is typical of people with hip fracture. This should be discussed in more detail.

Reply: The patients with hip fracture included in the study have been discussed further on p. 16, Para 3.

3. The actual SF36 Physical Component and Mental Component scores should be added to the results and the abstract.

Reply: The actual SF-36 PCS and MCS scores have been added in the result-section at p. 14, Para 1.
4. That there are 10 deaths over 2 years in the cases and nil in the controls suggests that there is probably residual confounding due to differences in general health status between cases and controls. The authors should discuss this or state that they believe this mortality is due to the hip fracture.

Reply: More deaths among patients than controls have been discussed p. 17, Para 1

5. The flow chart should show cases and controls separately.

Reply: The flow chart shows only the patients included in the study. The flow of the controls are not as straightforward as the flow of the patients, and are therefore not included in the figure.

3. Reviewer's report

Reviewer: Yea-Ing Shyu

• Minor But Essential Revisions
1. Please provide the rationale for assessing HRQOL and GQOL at the same time.

Reply: The rationale for assessing both HRQOL and GQOL in the same study has been further described in the introduction section p. 4, Para 2.

2. In the data collection procedure, please specify that the baseline data were collected by asking the subjects to recall the pre-fracture HRQOL and GQOL. This fact was not made clear until the discussion, which is too late.

Reply: The recall pre-fracture nature of the HRQOL and GQOL data have hopefully been clarified by adding recall in the section "Data collection procedure”, p.7, Para 1.
3. Were the subjects assessed for their cognitive function before responding to the questionnaire? How can we be confident about the validity of data obtained? Please clarify.

Reply: The patient’s cognitive function was assessed by a nurse or doctor. This has been added in p. 6, Para 1.

4. Who recruited and administered the questionnaire, what kind of training did the rater(s) receive? Please clarify.

Reply: Four trained osteoporosis – nurses recruited the patients and the controls, and administered the clinical assessments and the questionnaires. This has been added in p. 6, Para 1.

5. Please provide information on the sample estimates and power analysis. In addition, provide the reason for excluding subjects that dropped out during the 2 year period (26, 20 in the first year and 6 in the second year). This decision might bias the results. There are multiple ways of dealing with this attrition, such as the multiple data imputation method, or using the longitudinal data analysis method such as GEE or HLM that can use subjects for at least 2 data points. Why did the researcher choose the repeated measures MANOVA method over the other methods of analysis?

Reply: We choose to include all patients willing and capable of participating in the study during a two year period, based on the registered number of patients (ca. 225 per year) in the orthopedic ward during the years preceding the study. However, we expected more patients to be included in the study than the actual included patients. With regard to power analysis 100 patients should have been included in the study to reach a power of 80 %, based on SF-36, considering a change/difference of 10 point as clinical relevant and SD = 25. However, the inclusion of 97 patients in the study is also acceptable.

We choose to use the 61 patients still in the study at two year follow-up, due to the possibility to have an acceptable age- and gender matched control group for comparison, and thereby were the repeated MANOVA method chosen.
6. How was the number of co-morbidity measured? What were the diseases that were included? Were both chronic and acute diseases included? Please clarify.

*Reply:* The numbers of co-morbidity was measured by self-report, and the diseases included were; heart diseases, pulmonary diseases, neurological disorders, urogenital disorders, gastrointestinal disorders, endocrine disorders, inflammatory joint disorders, connective tissue disorders, cancer. This is hopefully clarified in p. 7, Para 2.

• Discretionary Revisions

7. In the discussion, different from the literature, this study did not find that BMD was a significant predictor for HRQOL. It would be nice if the explanation for this difference was added.

*Reply:* There is no clear explanation for this, and this has been added to the discussion section p.16, Para 2.

8. Can the researchers suggest a better patient-reported outcome measure based on the findings of this study? It seems that HRQOL was more sensitive to the impact of hip fracture than GQOL.

*Reply:* HRQOL covers the patient’s experience of their general state of health, while GQOL focused on overall well-being and satisfaction. The results revealed in our study with regard to the impact of the hip fracture on HRQOL and GQOL is therefore not necessarily surprising. To reach a broad subjective perspective both HRQOL and GQOL measures need to be addressed. Furthermore, is it possible to argue that a disease-specific questionnaire might reveal health-problem more specific for the patients with hip fracture. However, since comparisons with matched controls were a guiding principle in our study a generic HRQOL questionnaire was chosen.