Reviewer's report

Title: Health related quality of life 5 years after carpal tunnel release among patients with diabetes. A prospective study with matched controls.

Version: 2 Date: 10 June 2014

Reviewer: Jonas Ranstam

Reviewer's report:

This manuscript presents a matched cohort study on health related quality of life among patients with diabetes. I have some comments on the study design, statistical analysis, results presentation, and the conclusions.

Major Compulsory Revisions

1. The relation between the study design and the statistical analysis is unclear. First, 35 patients with diabetes and CTS were matched on age and gender with 31 CTS patients without diagnosed diabetes. This matching should be described in more detail, and it should be motivated why it was ignored in the statistical analysis as this can affect the validity of the results negatively, see e.g. Sjölander and Greenland. Ignoring matching variables in cohort studies - when is it valid and why? Stat Med 2013;32:4696-4708.

2. Second, the mixed model used to evaluate group differences in SF-36 and SOC should be described in more detail. The fixed factors are presented, but what factors were random? What assumptions were made regarding the distribution of the residuals and the variance-covariance matrix? Were these assumptions fulfilled?

3. The selection of adjustment variable should be described in more detail, especially with regard to the matching and causal relations between potential confounding factors, see e.g. Schisterman EF, Cole SR, Platt RW. Overadjustment bias and unnecessary adjustment in epidemiological studies. Epidemiol 2009;20:488-495.

4. Baseline measurements were included as fixed effects, but it is not clear if such an inclusion is meaningful, see e.g. Glymour et al. When is baseline adjustment useful in analyses of change? An example with education and cognitive change. Am J Epidemiol 2005;162:267-278. Please clarify.

5. The conclusion that SOC does not differ between patient groups seems to lack empirical support, be based on statistical insignificance, which indicates absence of evidence but not evidence of absence.

Minor Essential Revisions

6. Why were non-parametric methods used in combination with the mixed model analysis? This would be inconsistent if the reasons were related to non-Gaussian
distributions. Please clarify.

7. The results presentation should more clearly distinguish between clinical and statistical significance, and between what the authors have observed in the sample and inferred about the population represented by the sample. For example, the statement that "No correlation was demonstrated between SOC..." seems to represent a confusion between what was observed (a correlation of 0.26) and what was inferred (the hypothesis that the correlation is null in the superpopulation cannot be rejected).

Discretionary Revisions

8. The presentation of some p-values as >0.3 seems odd. Why not inform the reader about the actual p-value?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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

Declaration of competing interests:

I am employed by the same university and university hospital as the authors.