Reviewer's report

Title: Quality-of-life evaluation for advanced non-small-cell lung cancer: a comparison between vinorelbine plus gemcitabine followed by docetaxel versus paclitaxel plus carboplatin regimens in a randomized trial: Japan Multinational Trial Organization LC00-03 (BRI LC03-01)

Version: 1 Date: 7 September 2010

Reviewer: Prunella Blinman

Reviewer's report:

This paper reports a study of the quality of life of patients with non-small-cell lung cancer during a randomised trial. Whilst this is a relevant clinical question, my overall impression is the paper is too brief (1800 words), lacks sufficient methodological detail, and the discussion and conclusion do not flow from the results obtained from the study.

Major Compulsory Revisions

1. page 5-6, QOL assessment, Methods.
Each QOL instrument was described. Please clarify:
- how many times the patients completed the FACT-G
- were the QOL instruments completed in English or Japanese?
- have the FACT-Taxane & FACIT-Sp been validated in patients with lung cancer
- has FACT-Taxane been validated in regimens with vinorelbine?
- why was a minimum of 50% subscale completion chosen for the FACT-G (& not 80% as specified in the next sentence)

Suggest a Figure showing schema of parent trial & current QOL study.

2. page 6-7, Statistical considerations, Methods
Please explain:
- rationale for sample size of 200
- why ‘only 190 patients were potential candidates for the QOL study’
- provide power estimation
- been asked to enter since January 2004’?
- why the study was commenced mid-way through the trial
- what the FACIST scoring guidelines are
- what difference in QOL scores was considered to be clinically meaningful?
- how will the groups be compared eg comparisons of means, slopes etc
- if subgroup analyses were post-hoc or pre-specified
3. page 7-8, Results
Please clarify:
- why only 84 patients (& not the planned 200) entered this study
- why patients were excluded if <80% of any QOL instrument was completed because this contradicts statement in methods, referred to in comment (2)
- whether the patients in this study were similar to those in the parent study

4. Page 8, Results. Last sentence of results should state that there is no difference in QOL between the sexes, rather than they were similar.

5. Page 9, Discussion. ‘The present BRI LC03-01 study QOL evaluation demonstrates that patients treated with the VGD regimen generally experienced an improvement in their QOL compared with patients in the PC group, but only in terms of the FACT-Taxane questionnaire’ is misleading & does not reflect the results ie only a difference in slope of FACT-T.

5. Page 9, Discussion. ‘In terms of general health, patients receiving the VGD regimen had better QOL than those receiving PC treatment, as assessed by the FACT-L, FACT Taxane and FACIT-Sp scores’ does not follow from results ie mean scores were no different. Provide evidence to support or revise.

6. Page 9, Discussion. JMTO LC00-03, a randomized trial of the VGD and … and progression-free survival (median survival time, 5.5 versus 5.8 months)’- how does this relate to the results of the QOL study?

7. Page 9, Discussion. ‘We can be reasonably confident … was clinically meaningful,…’ doesn’t follow from results. What QOL improved? Clinically meaningful change in scores not defined. Provide evidence to support or revise.

8. Page 9, Discussion. ‘Furthermore, Fossella et al. investigated … as first-line chemotherapy’ not comparable to current study where vinorelbine & docetaxel were in the same regimen. Most importantly, the authors have not considered that vinorelbine can also cause peripheral neuropathy anywhere in the paper.

9. Page 10, Discussion. There are definitely more than one limitation to this study, suggest expand this part of the study & explain how the limitations of the study may affect the results?

10. Page 10, Discussion. Poor compliance with QOL …potentially producing biased results’. Not relevant to the results as the authors state that the study has good compliance, likely because only those patients who completed >=1 QOL assessment were included.

11. No discussion of strengths of study, & clinical & research implications.

12. Page 10, Conclusion. Doesn’t all follow from results and discussion.

Minor Essential Revisions
1. Page 4, study population, methods- please insert where the study was performed. ? did all centres participating in the parent trial participate, or just some?
2. Page 7, results- extra word QOL- ‘and four patients QOL filled in…’
3. page 7, results- suggest commence new paragraph @ ‘Table 1..’
4. page 8, results- suggest new paragraph @ ‘Compliance…’
5. Suggest use a Figure to explain the patient recruitment

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests