Reviewer's report

Title: Higher rate of skin rash in a phase II trial with weekly nanoparticle albumin-bound paclitaxel and cisplatin combination in Chinese breast cancer patients

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Reviewer: Valentina Nekljudova

Reviewer's report:

This paper evaluates the incidence rate of skin rash under weekly nab-paclitaxel treatment in combination with cisplatin in Chinese metastatic breast cancer patients and compares it with the rate of skin rash in western breast cancer patients reported in the literature. The main conclusion of the paper is that the incidence of skin rash is higher in the Chinese patients and that the albumin component of nab-paclitaxel may be the cause.

Although the question is interesting, there are following issues:

- Major Compulsory Revisions

1. It is absolutely not clear from the abstract that the rate of skin rash in western patients treated with nab-paclitaxel is taken from the literature and not from the western patients treated in the same trial. It also should be mentioned as a limitation in the discussion section.

2. The western patient skin rash rate itself is not given in the abstract, only a p-value is provided which depends not only on the effect size but also on the sample size and therefore standing alone tells nothing about the absolute difference.

3. It is not clear whether the analysis was performed after all patients completed (or discontinued) treatment or is it an unplanned analysis of a running trial.

4. In the discussion authors cite a review by Yamamoto[21] “including almost all studies related to nab-paclitaxel in breast cancer” saying that only approximately 4% patients developed skin rash globally, but the data in Table 2 on 229 western patients with nab-paclitaxel is taken from Table 5 of Yamamoto review which refers to only one particular study by Gradishar et al.(J Clin Oncol. 2005;23(31):7794–7803), with 3-weekly regimen of nab-paclitaxel. It should be mentioned explicitly. Authors should also explain the choice of this particular control group. Were no data on hypersensitivity reactions reported in other studies?

5. Authors should discuss the potential bias caused by the differences between treatment regimens in Chinese and western patients (weekly vs 3-weekly, additional cisplatin) as well as in the definition of the considered endpoint (“skin rash” in this paper, “hypersensitivity” in Gradishar et. al).
6. Confidence intervals for rates should be included.

- Minor Essential Revisions (not for publication)

1. Abstract, methods: “Patients who received a least” -> typo, “at least”.
2. Mislabeled references in Table 2: Yamamoto [20] (must be 21 as in “References” section), Guan et al. [21] (must be 22), Seidman [22] (must be 23).

**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 declare that I have no competing interests