Reviewer's report

Title: Trastuzumab without chemotherapy in the adjuvant treatment of breast cancer: subgroup results from a large observational study

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Reviewer: Guenther Steger

Reviewer's report:

This manuscript addresses the important question of adjuvant systemic therapy without standard chemotherapy in HER2-positive breast cancer patients. Since no valid data evaluated prospectively the authors have rightly chosen to do a retrospective analysis in a large patient cohort (n=3935). The results show that one relevant survival outcome as measured by relapse-free survival (RFS) clearly show that omitting standard chemotherapy in those patients lead to a significantly worse RFS at 3 and 5 years. The data for a potential difference in OS are less clear (with p= 0.052) and this might be due to the relatively small proportion of patients (n=232; 6%) receiving no standard chemotherapy for various and heterogenous reasons such as contraindications, or patient's wish.

The authors rightly and plausible conclude that trastuzumab + standard chemotherapy should thus remain the preferred adjuvant Treatment option for these patients. However, they also state that based on these results trastuzumab monotherapy "...seems to be a reasonable option.." and this Statement appears to be not really holstered by the data and results presented since metastatic relapse in breast cancer patients is still always incurable and leads ultimately to death despite of the fact that some patients can be successfully treated often for many years. Thus, for such a retrospective evaluation the significant difference in RFS is much more to be appriciated than the non-significant difference in OS despite the fact that a propensity score Analysis was done to correct for selection bias.

In conclusion the authors present important data for a routine setting in the adjuvant treatment decision making in HER2-positive breast cancer patients, the manuscript is well written and there are no major or other essential minor flaws but in order not to give a wrong message based on retrospective data the last sentences in the conclusions as well as in the Abstract must be rephrased from: "...seems to be a reasonable option offering favorable long-term outcomes...." to e.g. "...might be a reasonable option for selected patients and an appropriate prospective evaluaqtion is strongly warranted...
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