Bias in reporting of end points of efficacy and toxicity in randomized, clinical trials for women with breast cancer

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Abstract

Background Phase III randomized, clinical trials (RCTs) assess clinically important differences in end points that reflect benefit to patients. Here, we evaluate the quality of reporting of the primary end point (PE) and of toxicity in RCTs for breast cancer.

Methods PUBMED was searched from 1995 to 2011 to identify RCTs for breast cancer. Bias in the reporting of the PE and of toxicity was assessed using pre–designed algorithms. Associations of bias with the Journal Impact Factor (JIF), changes in the PE compared with information in ClinicalTrials.gov and funding source were evaluated.

Results Of 164 included trials, 33% showed bias in reporting of the PE and 67% in the reporting of toxicity. The PE was more likely to be reported in the concluding statement of the abstract when significant differences favoring the experimental arm were shown; 59% of 92 trials with a negative PE used secondary end points to suggest benefit of experimental therapy. Only 32% of articles indicated the frequency of grade 3 and 4 toxicities in the abstract. A positive PE was associated with under–reporting of toxicity.

Conclusion Bias in reporting of outcome is common for studies with negative PEs. Reporting of toxicity is poor, especially for studies with positive PEs.