Bevacizumab (Avastin®) in combination with chemotherapy as second-line therapy for HER2-negative, locally recurrent or metastatic breast cancer that has progressed after first-line treatment with bevacizumab plus chemotherapy

Ludwig Boltzmann Institut fuer Health Technology Assessment (LBI-HTA)

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Authors' conclusions
Bevacizumab (Avastin®) is a recombinant monoclonal antibody that binds to vascular endothelial growth factor (VEGF). By inhibiting VEGF receptor binding, bevacizumab prevents the growth and maintenance of tumour blood vessels. Bevacizumab is indicated in different types of cancer and in various combinations with other drugs. To date, bevacizumab has not been approved either by the EMA or the FDA for the second-line treatment of patients with HER2-negative, locally recurrent or metastatic breast cancer after first-line treatment with bevacizumab plus chemotherapy, i.e. the indication investigated by the TANIA trial. The TANIA trial compared second-line single-agent chemotherapy either alone or with bevacizumab in a total of 494 patients. Analyses of median progression-free survival showed a gain of 2.1 months for patients receiving further bevacizumab, resulting in a risk reduction for progression or death by any cause of 25%. The objective response rate was, with an absolute difference of 4.1%, slightly higher in the combination group than in the chemotherapy-alone group. There was no difference in overall survival between the two groups; however, at the time of interim analyses, overall survival results were immature. Adverse events (AEs) of grade 3 or worse were more frequent in patients of the combination group (59%) than in patients of the chemotherapy group (46%). Serious AEs also occurred more frequently in the combination group (25%) than in the chemotherapy-alone group (18%). The death of 2% of patients in each group of the TANIA trial was attributed to AEs. The addition of bevacizumab to standard second-line chemotherapy provides only modest benefits for patients with locally recurrent or metastatic breast cancer and no improvement in overall survival was ascertained. Benefits, harms and treatment costs of this therapy must be weighed against each other accurately, especially since bevacizumab is not (yet) approved for the indication in question.

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