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Title **Avastin for Age-Related Macular Degeneration. Rapid Assessment**

Agency **LBI of HTA, Ludwig Boltzmann Institute of Health Technology Assessment**
Garnisongasse 7/20, AT-1090 Vienna, Austria;
Tel: +43 1 236 8119 0, Fax: +43 1 236 8119 99; office@hta.lbg.ac.at, http://hta.lbg.ac.at

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Aim

To clarify the safety risks for age-related macular degeneration (AMD) patients treated with Avastin and to estimate the liability risks for the physicians and institutions providing care.

Conclusions and results

The incidence of neovascular AMD increases rapidly with age. The US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) have approved the monoclonal antibodies Pegaptanib (Macugen®) and Ranibizumab (Lucentis®) for intravitreal therapy to inhibit vascular endothelial growth factors (VEGF). A third drug, Bevacizumab (Avastin®), has not been approved for this indication. However, because it is 30 times less expensive than Lucentis it is used "off-label" much more in clinical settings than the approved drug Lucentis. Chemically, Ranibizumab, is a fragment of the Bevacizumab protein. Both substances were developed by Genentech laboratories and show similar pharmacodynamics although they have different half-lives.

Analysis of the studies on the safety of intravitreous AMD therapy by Bevacizumab does not provide valid evidence either for or against the use of Avastin. Trials have been methodologically inadequate and insufficient to draw firm conclusions. Specifically, the evaluation of treated and untreated patients, information on diagnoses and AMD stages, incomplete reporting on side effects, and varying numbers of patients in followup limit the validity of the evidence. However, based on preliminary data, administration of Bevacizumab (Avastin) is appraised as promising, since the monitored side effects are of only moderate clinical relevance. Nevertheless, only a comprehensive randomized comparative clinical trial of Bevacizumab and Ranibizumab could produce final, valid results.

Methods

This report is based on a simple literature review, using MEDLINE and EMBASE. Results were selected using inclusion and exclusion criteria, eg, medical indications, clinical trials, interventions, and number of participants. Also, 21 published clinical trials on safety and side effects of Avastin and 56 partially unpublished references concerning the topic have been evaluated.

Written by Adlbrecht C and Wild C, LBI of HTA, Austria

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