INAHTA Briefs

Issue 2010/057

Title **Ranibizumab and Pegaptanib for the Treatment of Age-Related Macular Degeneration: A Systematic Review and Economic Evaluation**

Agency **NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre**
Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;
Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.uk

Reference Volume 12.16. ISSN 1366-5278. www.hta.ac.uk/project/1528.asp

Aim

To assess the clinical and cost effectiveness of ranibizumab and pegaptanib for subfoveal choroidal neovascularization (CNV) associated with wet age-related macular degeneration (AMD).

Conclusions and results

Patients with AMD of any lesion type benefit from treatment with pegaptanib or ranibizumab on measures of visual acuity when compared with sham injection and/or photodynamic therapy (PDT). Patients who continued treatment with either drug appeared to maintain benefits after 2 years of follow-up. When comparing pegaptanib and ranibizumab, the evidence was less clear due to the lack of direct comparison through head-to-head trials and the lack of opportunity for indirect statistical comparison due to heterogeneity. Cost-effectiveness analysis showed that the two drugs offered additional benefit over the comparators of usual care and PDT, but at increased cost. The VISION study reported a combined analysis of two randomized controlled trials (RCTs) of pegaptanib [0.3 mg (licensed dose), 1.0 mg and 3.0 mg] versus sham injection in patients with all lesion types. Three published RCTs (MARINA, ANCHOR, FOCUS) and an unpublished RCT (PIER) of ranibizumab were identified. Significantly more patients lost less than 15 letters of visual acuity at 12 months with pegaptanib or ranibizumab than sham injection or, in the case of ranibizumab, PDT. The proportion of patients gaining 15 letters or more was statistically significantly greater with pegaptanib for doses of 0.3 and 1.0 mg but not for 3.0 mg, and for ranibizumab compared with sham injection or PDT. This was also statistically significant for 0.5 mg ranibizumab plus PDT compared with PDT plus sham injection. Pegaptanib patients lost statistically significantly fewer letters after 12 months of treatment than the sham group. In MARINA and ANCHOR trials, ranibizumab patients gained letters of visual acuity at 12 months, whereas patients with sham injection or PDT lost about 10 letters ($p < 0.001$). Adverse events were common for both pegaptanib and ranibizumab, but most were mild to moderate. Drug costs for 1 year of treatment were estimated as 4626 pounds sterling (GBP) for pegaptanib and GBP 9134 for ranibizumab. Non-drug costs accounted for an additional GBP 2614 for pegaptanib and GBP 3120 for ranibizumab. Further costs are associated with the management of injection-related adverse events, from GBP 1200 to GBP 2100. For pegaptanib compared with usual care, the incremental cost-effectiveness ratio (ICER) ranged from GBP 163 603 for the 2-year model to GBP 30 986 for the 10-year model. Similarly, the ICERs for ranibizumab for patients with minimally classic and occult non-classic lesions, compared with usual care, ranged from GBP 152 464 for the 2-year model to GBP 25 098 for the 10-year model. See Executive Summary link at www.hta.ac.uk/project/1528.asp.

Recommendations

See Executive Summary link at www.hta.ac.uk/project/1528.asp.

Methods

See Executive Summary link at www.hta.ac.uk/project/1528.asp.

Further research/reviews required

1) Trials to compare pegaptanib with ranibizumab and bevacizumab, and the role of verteporfin PDT in combination with these drugs. 2) A study to assess adverse events outside the proposed RCTs. 3) Studies to determine the optimal dosing regimes of these drugs and the benefits of re-treatment after initial treatment. 4) Research into health-state utilities and their relationship with visual acuity and contrast sensitivity, the relationship between duration of vision loss and the quality of life, and functional impact of vision loss. See Executive Summary link at www.hta.ac.uk/project/1528.asp.

Written by Dr Jill Colquitt, University of Southampton, NETSCC, United Kingdom

ISSN 1654-501X