Title **Clinical Effectiveness and Cost Utility of Photodynamic Therapy for Wet Age-Related Macular Degeneration: A Systematic Review and Economic Evaluation**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

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Aim

To establish the clinical and cost effectiveness of photodynamic therapy (PDT) for the neovascular form of wet age-related macular degeneration (AMD) relative to current practice and in relation to current licensed indications.

Conclusions and results

The Treatment of Age-Related Macular Degeneration with Photodynamic Therapy (TAP), trial found consistent evidence at 1 and 2 years that verteporfin PDT resulted in less deterioration in visual acuity in the eye randomized than in the placebo-treated eye. This effect was statistically significant and clinically important. The Verteporfin in Photodynamic Therapy (VIP) trial showed a similar result. An increase in adverse events was associated with verteporfin PDT. Lack of heterogeneity between the results of TAP and VIP invited re-examination of the assumption that the nature of the wet AMD neovascular lesions has as much influence on the relative effect of verteporfin PDT as was predicted on the basis of an assessment of clinical heterogeneity. The results of subgroup analyses should be treated with caution. The impact of reduced deterioration in visual acuity should be based on whole trial estimates of effect. The report presents estimates of quality-adjusted life-years from cost-effectiveness studies, an economic model of base-case estimates, and sensitivity analyses. None of the estimates concerned wet AMD in the worse seeing eye. More favorable estimates of cost utility were only found in models extrapolating beyond 2 years, the limit of RCT data.

Recommendations

The balance of beneficial and disbeneficial clinical effects measured in the RCTs appears to favor verteporfin PDT. However, avoiding deterioration in visual acuity does not equate directly with improving patient function and quality of life. Also, function depends on vision in both eyes, not just the impact of wet AMD on one eye, and this needs be addressed. We believe that verteporfin PDT is an inefficient use of healthcare resources.

Methods

Randomized controlled trials (RCTs) and economic evaluations on clinical effectiveness and cost utility of PDT in AMD were systematically reviewed. Electronic databases, HTA and Internet sites, reference lists, conference abstracts, and the Novartis Industry submission on RCTs and economic evaluations were searched up to Aug/Sept 2001. Synthesis was mainly qualitative for clinical effectiveness and cost utility. Cost utility was analyzed. PDT with best supportive care was compared with best supportive care only, using clinical effectiveness data from one RCT, published utility and treatment cost studies, and blindness cost estimates.

Further research/reviews required

A large, multicenter, publicly funded, pragmatic, double-blind RCT is needed with parallel health economic evaluation to assess the impact of PDT on visual acuity, adverse events, and quality of life. There is no indication of the relationship between benefits and costs where wet AMD affects the worse seeing eye first. Treatment of wet AMD, with verteporfin, other types of PDT, and other new technologies are under investigation and should be kept under close review.

Written by Dr Catherine Meads, Department of Public Health & Epidemiology, University of Birmingham, UK