A Cost-Effectiveness Analysis of the Randomized Trial Evaluating Ranibizumab Plus Prompt or Deferred Laser or Triamcinolone Plus Prompt Laser for Diabetic Macular Edema.

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Abstract:

Purpose: The costs of new treatment strategies for diabetic macular edema (DME) have the potential to add millions of dollars to the health care system; therefore, policymakers need to determine if this cost is justified by the effectiveness of treatment. We present a cost-effectiveness analysis (CEA) of the four strategies evaluated in a recent randomized clinical trial (Protocol I).

Methods: We constructed a Markov model to replicate Protocol I using a microsimulation approach to estimation. The Markov cycle was one month, the model duration was one year (based on the time to primary outcome in Protocol I), and we took the payer’s perspective. We based the clinical pathway on the management algorithms outlined in Protocol I. Subjects were assigned initial characteristics of visual acuity (VA) and macular thickness (OCT) based upon the participants in the clinical trial. The simulated participants accrued costs upon cycle completion, and changes in VA and OCT were assigned based upon the effectiveness in the designated treatment arm. Treatment complications were also based upon the clinical trial experience. Cost information was obtained via literature search and from the Barnes Retina Institute billing department. We present cost, effectiveness as measured by change in letters correct, and the incremental cost-effectiveness ratio (ICER). The model's internal validity was established by comparison to Protocol I outcomes.

Results: Preliminary data gives expected values for groups 1 (laser), 2 (ranibizumab plus prompt laser), 3 (ranibizumab plus deferred laser), and 4 (steroid plus laser). Expected costs in groups 1-4 were $3,232, $21,200, $22,623, and $3,785, respectively. The expected effectiveness values in groups 1-4 were 4, 7.4, 8.5, and 4 letters gained, respectively. ICER values in terms of dollars per VA letter were 21,944 (4 vs 1), 5,169 (2 vs 4), and 1,318 (3 vs 2). Similar ICER values calculated for pseudophakic subgroups were 39 (4 vs 1), -13,913 (3 vs 4), and 29 (2 vs 3).

Conclusions: The use of ranibizumab in treatment of DME results in an increase on nearly one line of vision over laser alone, or laser plus steroids; however, policymakers must also be aware that there is substantial cost to gain this improvement. Further analysis concerning important subgroups might improve our understanding of those who might most benefit from this therapy.


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