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Title **Imatinib for the Treatment of Patients with Unresectable and/or Metastatic Gastrointestinal Stromal Tumors: Systematic Review and Economic Evaluation**

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Aim

To assess the clinical and cost effectiveness of imatinib in treating unresectable and/or metastatic, KIT-positive, gastrointestinal stromal tumors (GISTs), relative to current standard treatments.

Conclusions and results

Evidence from published uncontrolled trials involving 187 patients, and from abstracts reporting similar uncontrolled trials involving 1700 patients, indicates that approximately 50% of imatinib-treated individuals with advanced GIST experience at least a 50% reduction in tumor mass. Although useful data are accumulating, it is not possible to predict which patients may respond in this way. Also identified were 15 studies where possible GIST patients had been treated with therapies other than imatinib or best supportive care. Imatinib-treated patients experienced relatively mild adverse effects. Overall, imatinib was well tolerated. Patients on the highest dose regimen may experience dose-limiting drug toxicity. The Novartis economic evaluation of imatinib for unresectable and/or metastatic GIST was assessed. A modified Novartis model estimated the cost per quality-adjusted life-year (QALY) in British pounds (GBP) at GBP 85 224 after 2 years, GBP 41 219 after 5 years, and GBP 29 789 after 10 years. The results from a new Birmingham model were also within the range of estimates from the modified Novartis model.

Methods

As there were no randomized trials that directly compared imatinib with the current standard treatment in patients with advanced GIST, this review included nonrandomized controlled studies, cohort studies, and case series that reported effectiveness results of treatment with imatinib and/or other interventions in patients with advanced GIST. The effectiveness assessment was based on a comparison of results from imatinib trials and results from studies of historical control patients. Economic evaluation was based mainly on an assessment and modification (when judged necessary) of a model submitted by Novartis.

Further research/reviews required

More emphasis should be placed on quality of life in trials involving patients with advanced malignancy. Adverse events should be reported to facilitate intertrial comparisons, and long-term followup of adverse events is needed. Patients diagnosed with GIST are a heterogeneous group. Subgroup analysis concerning which, if any, patient types respond better or worse to imatinib is needed. Many uncertainties surround imatinib prescription, eg, duration of treatment, dose, drug resistance, and the optimum time to give the drug. Ongoing trials may resolve some of these uncertainties, and ongoing trials on adjuvant therapy in patients with primary disease may answer the question of timing. Secondary research, eg, an update of this systematic review, is recommended when ongoing trials reach completion.

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