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Title **The Clinical Effectiveness and Cost Effectiveness of Topotecan for Small Cell Lung Cancer: A Systematic Review and Economic Evaluation**

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Aim

To assess the clinical and cost effectiveness of topotecan as second-line treatment for small cell lung cancer (SCLC).

Conclusions and results

Topotecan appeared to be better than best supportive care (BSC) alone in terms of improved survival, and was as effective as cyclophosphamide, Adriamycin (doxorubicin), and vincristine (CAV) and less favorable than intravenous (IV) amrubicin in terms of response. Oral topotecan and IV topotecan showed similar efficacy. Topotecan offers additional benefit over BSC, but at increased cost. Incremental cost-effectiveness ratios (ICERs) for IV topotecan, compared to BSC, were high and suggest it is unlikely to be a cost-effective option. The ICER for oral topotecan is at the upper extreme of the range that the NHS regards as cost effective. We identified 434 references, of which 5 were included in the clinical effectiveness review. In these trials, topotecan was compared with BSC, CAV, or amrubicin, or oral topotecan was compared with IV topotecan. No economic evaluations were identified. We found no statistically significant differences between groups when IV topotecan was compared with either CAV or oral topotecan for overall response rate (ORR). The response rate was significantly better in participants receiving IV amrubicin than in those receiving a low dose of IV topotecan (38% versus 13%, respectively, p = 0.039). We found a statistically significant benefit favoring oral topotecan compared with BSC (HR 0.61, 95% CI 0.43 to 0.87, p = 0.01). Drug acquisition costs for 4 cycles of treatment were estimated at 2550 pounds sterling (GBP) for oral topotecan and GBP 5979 for IV topotecan. Non-drug treatment costs accounted for an additional GBP 1097 for oral topotecan and GBP 4289 for IV topotecan. Total costs for the modeled time horizon of 5 years were GBP 4854 for BSC, GBP 11 048 for oral topotecan, and between GBP 16 914 and GBP 17 369 for IV topotecan (depending on assumptions regarding time progression). Life expectancy was 0.4735, 0.7984, and 0.7784 years for BSC, oral topotecan, and IV topotecan respectively. Total quality-adjusted life-years (QALYs) were 0.2247 and 0.4077 for BSC and oral topotecan respectively, resulting in an ICER of GBP 33 851 per QALY gained. Total QALYs for IV topotecan were between 0.3875 and 0.4157 (depending on assumptions regarding time progression) resulting in an ICER between GBP 74074 and GBP 65 507 per QALY gained.

Recommendations

See link www.hta.ac.uk/project/1754.asp.

Methods

See link www.hta.ac.uk/project/1754.asp.

Further research/reviews required

It is unlikely that any further RCTs of topotecan compared with BSC will be ethically acceptable, nor is it likely there will be a need for further comparisons with CAV therapy. Little can be gained from further study of the effectiveness of IV versus oral topotecan. However, when the ongoing RCTs of topotecan versus amrubicin report, it would be desirable to update the current review. Further research is required on the quality of life (QoL) of patients with relapsed SCLC, to identify the impact of disease progression on QoL. In patients receiving active treatment, further research is required on the impact of complete or partial response and the impact of treatment-related adverse events on QoL.

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