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Title **Health Benefits of Antiviral Therapy for Mild Chronic Hepatitis C: Randomized Control Trial and Economic Evaluation**

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Aim

To determine whether the combination of interferon alpha and ribavirin is more effective than no treatment for mild chronic hepatitis C virus (HCV) infection.

Conclusions and results

Virology: In the treatment group, 32 of 98 (33%) patients achieved a sustained viral response (SVR). Patients infected with genotype 1 had a lower SVR than those infected with genotype non-1. No patients who failed to achieve a 2-log drop in viral load at 12 weeks achieved a SVR.

HRQOL: Compared to baseline values, health-related quality of life (HRQOL) fell during treatment and rose with treatment cessation. Patients having a SVR showed modest improvements in HRQOL at 6 months post treatment.

Cost effectiveness: The gain in HRQOL for patients with mild hepatitis C, who were treated and had a SVR, offset the HRQOL reduction during treatment. The overall lifetime cost per QALY gained for treatment compared to no treatment for mild hepatitis C was approximately GBP 20 000 per QALY. The mean cost per QALY gained for patients aged 40 years with genotype non-1 was GBP 5000. For patients aged 40 years with genotype 1, treatment at a mild stage reduced QALYs (-0.05) and was not cost effective. Cost effectiveness improves for those who begin treatment at a younger age; treatment was cost effective for patients with genotype 1 who were aged 20 years at treatment. The intervention was not cost effective for patients aged 65 years or over, irrespective of genotype.

Using viral kinetics to determine early cessation of treatment improved the cost effectiveness of treatment for mild hepatitis C, but the intervention was still only cost effective for patients with genotype non-1.

The model used efficacy estimates from the literature to estimate the cost effectiveness of treating mild patients with pegylated interferon alpha and ribavirin, and demonstrated that this treatment would be cost effective at a mild stage for all hepatitis C patients with genotype non-1 and those with mild hepatitis, due to hepatitis C genotype 1, aged <65 years.

Recommendations

For patients with mild hepatitis C and viral genotype non-1 (genotypes 2 or 3), interferon alpha and ribavirin treatment is effective and cost effective at the cost per QALY threshold used by NHS policymakers. Using viral kinetic data to target treatment at likely SVR cases further improves cost effectiveness. For patients aged <65 years with genotype non-1 and those with genotype 1, the most cost-effective strategy is to treat patients with mild disease. Using liver biopsy to assess disease severity no longer appears justified.

For hepatitis C patients aged >65 years with mild hepatitis due to genotype 1 infection, the low SVR following antiviral treatment means that the cost of intervention is not justified. In these patients it is more cost effective to monitor mild disease, and treat only patients who progress to moderately severe hepatitis C. Patients aged >65 years with genotype 1 infection should be offered liver biopsy to identify moderate or severe disease, which should be treated. Patients in this age group with mild disease should not be treated.

Methods

See Executive Summary link above.

Further research/reviews required

- Long-term HRQOL for patients who have had a SVR
- Impact of pegylated interferon alpha and ribavirin on SVRs HRQOL and health service costs
- Use of predictive tests based on pharmacogenomics to target therapy to those most likely to respond
- Results of not using liver biopsy before treatment in patients with genotype non-1 and younger patients with genotype 1 (<65 years), and the impact of this strategy on costs and outcomes
- Role of noninvasive tests to identify those in the >65 year old group with genotype 1 infection, with more advanced fibrotic disease (> stage 2), who need treatment.

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