Serologic survey for control of hepatitis C in haemodialysis patients: third-generation assays and analysis of costs


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Control of hepatitis C virus (HCV) by using third generation screening assays (ELISA and immunoblot) among chronic haemodialysis (HD) patients.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
190 HD patients (111 males and 79 females) attending a single dialysis unit. The mean age was 62.6 (+

Setting
Hospital setting. The study was carried out in Lecco, northern Italy.

Dates to which data relate
Effectiveness and resource data were collected for the study in May 1994. No price dates were specified.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Costing was undertaking alongside the same patient sample as that used in the effectiveness study. It is not clear whether costing was taken prospectively or retrospectively.

Study sample
No power calculation was conducted to determine sample size. A serologic survey for control of hepatitis C was performed in 190 HD patients attending a single dialysis unit, using second- and third-generation assays.

Study design
Single centre case series study. Patients were tested by second- and third-generation screening assays (ELISA-2 and ELISA-3). All ELISA-2 positive patients were tested by second-generation confirmatory assay (RIBA HCV 2.0 SIA) and if results were equivocal, a third generation confirmatory assay (RIBA HCV 3.0 SIA) and RT-PCR was applied. If
the ELISA-2 positives were matched with RIBA HCV 2.0 SIA-positive patients, a subgroup were randomly selected and evaluated by RIBA HCV 3.0 SIA. Positive sera detected through ELISA-3 were analysed by RIBA HCV 2.0 and 3.0 SIA tests by RT-PCR. Serum AST and ALT activities, determined by spectrophotometry every 3 months, were retrospectively evaluated after the onset of HD. A follow-up sample from each patient was obtained 1 month later. It was assumed that all 190 patients were tested semiannually for anti-HCV whereas confirmatory assays on these patients were done once a year.

**Analysis of effectiveness**
The analysis of the study was based on intention to treat. The main health outcomes were improvement in the quality of care and improvement of both sensitivity and specificity of the HCV tests.

**Effectiveness results**
The prevalence of anti-HCV antibodies was 25% (48/190) when tested by third generation tests compared to 28% (53/190) in the second-generation testing group. 56% (9/16) of patients showing uncertain findings by second-generation tests gave unequivocal results by third-generation assays. The median duration of HD treatment was 59 and 36 months, for anti-HCV positive and negative patients, respectively. Median duration of HD treatment and raised aminotransferase levels were positively associated (P=0.004 and P=0.012, respectively) with anti-HCV detected by third-generation assays. Among the 190 HD patients, 25 (13%) showed raised AST and ALT concentrations; 16 of them (64%) exhibited multiple peaks. 13 out of the 25 (52%) were anti-HCV positive and, of these, 9 were positive by second-generation tests, and 4 gave unclear results.

**Clinical conclusions**
Third generation screening and confirmatory assays seemed extremely useful in the serologic survey for control of hepatitis C in haemodialysis centres.

**Modelling**
None.

**Measure of benefits used in the economic analysis**
The main health outcome was improvement in the quality of care and improvement of both sensitivity and specificity of the tests.

**Direct costs**
Costs were not discounted. Costs and quantities were reported separately. Only costs/quantities additional to standard care were included. Labour costs were not included in the analysis as they were considered negligible. The costs of serologic tests were provided and these were based on hospital costs. Quantities and costs were based on actual data. It is likely that 1994 prices were used, although this was not explicitly stated.

**Statistical analysis of costs**
Not carried out.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).
Sensitivity analysis
Not carried out.

Estimated benefits used in the economic analysis
Using third-generation assays resulted in the detection of more ELISA anti-HCV positive patients on chronic HD treatment. There was an increase of prevalence of anti-HCV antibody from 25% to 28% in the HD population.

Cost results
The total cost of the serologic survey was $18,866 by third-generation assays and $17,220 by second-generation assays in the HD patients per year. Hence the incremental cost of third-screening assays was $1,646 per year. No discounting was undertaken.

Synthesis of costs and benefits
Costs and benefits were not combined by the authors.

Authors' conclusions
The third-generation tests had higher sensitivity and specificity than the second-generation tests and were also more costly. Third-generation assays confirmed the association of duration of HD treatment and raised aminotransferase levels with anti-HCV antibody.

CRD COMMENTARY - Selection of comparators
The comparator used was second-generation testing. You, as a database user, should consider if this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
This was based on improvements in the quality of care and of both sensitivity and specificity of the tests. Results are likely to be internally valid.

Validity of estimate of costs
Resource quantities were reported separately from prices. However quantity/cost estimation was not clear.

Other issues
The study did not present the results clearly.

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