Cost-effectiveness analysis of serum vancomycin concentration monitoring in patients with hematologic malignancies

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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
Serum vancomycin concentration monitoring in patients with hematologic malignancies.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was a cohort of immunocompromised male and female febrile patients with hematologic malignancies. The average age was 50.2 years (+

Setting
Hospital. The economic analysis was carried out in Salamanca, Spain.

Dates to which data relate
The main effectiveness data were extracted from a clinical trial conducted in 1996. Resource and cost data were mainly derived from 1996 sources. The price year was not given.

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

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the economic analysis.

Study sample
A cohort of 77 immunocompromised febrile patients were entered into the trial. Thirty-seven patients (29 male) were assigned to the TDM group and 33 were assigned to a control group (21 male). Power calculations to determine the sample size were not undertaken.

Study design
The study was a randomized controlled trial with patients being randomized by means of a table of random numbers. The duration of the follow-up was from enrollment until 5 days after vancomycin therapy had been discontinued. The
loss to follow-up included 7 patients who were excluded from the final analysis because they did not meet the inclusion criteria. Four did not complete 96 hours of vancomycin therapy, 1 was transferred to the intensive care unit, 1 did not complete therapy because of the development of serum creatinine levels above 2mg/dl in <24 hours and 1 was excluded because of insufficient data.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only. The primary health outcomes used in the analysis were the estimates of the length of hospital stay, the clinical response, the number of days of fever, the time required to reach apyrexia, the duration of the vancomycin therapy and the incidence of nephrotoxicity.

Effectiveness results
The effectiveness results for the TDM and control groups were as follows:

- Treatment duration: 18.5 days (+/- 8.1) vs. 19.8 days (+/- 9.6)
- Hospital stay: 24.5 days (+/- 15.5) vs. 24.1 days (+/- 15.0)
- Global clinical response: 24 cases of improvement, 7 indeterminate cases and 6 failures in the TDM group and 19 improvements, 5 indeterminate cases and 9 failures in the control group.
- Number of days of fever: 5.6 (+/- 4.7) vs. 7.1 (+/- 5.3)
- Number of days necessary to reach apyrexia: 4.1 (+/- 3.9) vs. 5.4 (+/- 4.9)
- Percentage of nephrotoxicity: 13.5% vs. 42.4%

Measure of benefits used in the economic analysis
The benefits measured were: the length of hospital stay, the clinical response, the number of days of fever, the time required to reach apyrexia, the duration of the vancomycin therapy and the incidence of nephrotoxicity.

Direct costs
The costs of the serum vancomycin assay, the time spent on each monitoring task and the time spent by clinical pharmacists were included in the analysis. The fixed costs were not included because serum vancomycin monitoring accounts only for 5% of total drug monitoring. Whether quantities/costs were analysed separately was not stated. The costs were not discounted. The quantity/cost boundary adopted was the hospital. The date to which the price data refer was not stated.

Statistical analysis of costs
Chi-squared test, Fisher exact test, Mann-Whitney test for continuous variables and p value < 0.05.

Currency
Spanish Peseta converted and rounded off to the nearest US $ ($1 = 130 Pesetas).

Sensitivity analysis
Not stated.

Estimated benefits used in the economic analysis
Treatment duration: 18.5 days (+/- 8.1) vs. 19.8 days (+/- 9.6)
Hospital stay: 24.5 days (+/- 15.5) vs. 24.1 days (+/- 15.0)

Global clinical response: 24 cases of improvement, 7 indeterminate cases and 6 failures in the TDM group and 19 improvements, 5 indeterminate cases and 9 failures in the control group.

Number of days of fever: 5.6 (+/- 4.7) vs. 7.1 (+/- 5.3)

Number of days necessary to reach apyrexia: 4.1 (+/- 3.9) vs. 5.4 (+/- 4.9)

Percentage of nephrotoxicity: 13.5% vs. 42.4%

Cost results
The total cost of a vancomycin monitoring was estimated to be $46 made up as follows: $30 for assay, $4 for nursing time and $12 for time invested by the clinical pharmacist.

Synthesis of costs and benefits
The estimated benefits and costs were not combined. An incremental analysis was performed. The incremental cost-effectiveness of the vancomycin TDM was estimated to be $435 per case of nephrotoxicity prevented.

Authors’ conclusions
A decreased incidence of nephrotoxicity provides evidence of a real clinical benefit to patient management in patients with hematologic malignancies. The TDM for vancomycin therapy in the high-risk population studied has been shown to be a cost-effective procedure.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator is clear. For vancomycin, controversy remained as to when monitoring is appropriate or whether it is necessary. No cost-effectiveness analysis of TDM for vancomycin therapy had been conducted before.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis is likely to be internally valid. The data have not been used selectively to prove the cost-effectiveness of TDM for vancomycin therapy.

Validity of estimate of costs
Adequate details of methods of quantity/cost estimation were given. Costs were not itemized.

Other issues
The authors’ conclusions were justified, given the uncertainties in the data. The issue of generalisability to other settings was not addressed. Appropriate comparisons, however, were made with other studies. The results were not presented selectively. A synthesis of benefits and costs could have been reported in a more detailed way.

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