A pilot study to evaluate the cost-effectiveness of ondansetron and granisetron in fractionated total body irradiation

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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
Intravenous granisetron 3 mg (in a single dose), with a second dose on failure versus twice-daily oral ondansetron 8 mg given 30 minutes before each fraction in order to prevent radiation-induced emesis during fractionated total body irradiation in patients undergoing total body irradiation prior to bone marrow transplantation for leukaemia or lymphoma.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients aged over 18 years who underwent total body irradiation prior to bone marrow transplantation for leukaemia or lymphoma.

Setting
Hospital. The economic study was carried out in London, UK.

Dates to which data relate
The dates of the effectiveness and resource use data were not specified. The date for the prices used was early 1993.

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

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

Study sample
Power calculations were not used to determine the sample size. The study consisted of 26 patients randomly assigned to either the ondansetron group (n=13) or the granisetron group (n=13). One patient in the granisetron group was excluded because of protocol violation.

Study design
This pilot study was a randomised controlled trial, carried out in a single centre. A six-sided dice was used for the random allocation of the treatments to patients. The duration of follow up was 3 or 4 days.

**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 response rate within the first 24 hours from the start of irradiation and overall response rate over the 3-4 day follow-up period. Complete response was defined as a health state with no vomiting, or only mild nausea, whereas major response was defined as a health state with one emetic episode or moderate-severe nausea.

**Effectiveness results**
The ondansetron group had a complete or major response rate of 77% (10/13) over the 3-4 day follow-up period (defined as overall response) as opposed to 50% (6/12) for the granisetron group (P= 0.226, with 95% CI: -0.095 to 0.633). The ondansetron group had a complete or major response rate of 77% (10/13) within the first 24 hours from the start of irradiation versus 67% (8/12) for the granisetron group (95% CI: -0.25 to 0.454).

**Clinical conclusions**
The study revealed that “the response rate in the ondansetron group was higher than that in the granisetron group. To confirm this a larger prospective randomised study would be required. Such a trial should be multicentre in order to recruit adequate numbers of patients.”

**Measure of benefits used in the economic analysis**
Response rate was the main benefit measure.

**Direct costs**
Not all resource use quantities were reported separately. The costs of regimens of medications used were calculated including the extra doses used for some patients. The perspective adopted in the cost analysis was not explicitly specified. The sources of cost data were not given. 1993 price data were used.

**Indirect Costs**
Not included.

**Currency**
UK pounds sterling (£).

**Sensitivity analysis**
Not performed.

**Estimated benefits used in the economic analysis**
The ondansetron group had a complete or major response rate of 77% (10/13) over the 3-4 day follow-up period (defined as overall response) as opposed to 50% (6/12) for the granisetron group (P= 0.226, 95% CI: -0.095 to 0.633). The complete plus major response rates for granisetron every 24 hours and every 36 hours were estimated to be 66.7% and 66.7%, respectively.

**Cost results**
The ondansetron group had an average cost (per patient) of 54 versus 48 for the granisetron group. The average cost for
granisetron every 24 hours and every 36 hours was estimated to be 108 and 72, respectively.

**Synthesis of costs and benefits**
Costs and benefits were not combined.

**Authors' conclusions**
The authors concluded that "The dose scheduling [the authors] used for granisetron can not be recommended on the basis of outcome. Granisetron needs to be given more frequently, but this leads to an increase in cost. ... Although the twice-daily ondansetron in this study had a 77% response, which was maintained throughout the 3-4 day follow-up period, a failure rate of 23% might suggest further room for improvement".

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator. It was the standard treatment in the context in question at the study site. You should consider whether this is a widely used health technology in your own setting.

**Validity of estimate of measure of benefit**
Despite the use of a randomised design, the internal validity of the effectiveness results may be weakened by the small sample size. The study groups were not compared in terms of demographic and medical features.

**Validity of estimate of costs**
Resource use quantities were not reported separately from the costs.

**Other issues**
Given the small sample size, and the lack of both sensitivity analysis and statistical analysis of the costs, the results need to be treated with some caution. The issue of generalisability to other settings or countries was not addressed.

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