High dose intravitreal ganciclovir for CMV retinitis: a shelf life and cost comparison study

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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
High dose intravitreal ganciclovir (freshly made 20 mg/ml solution stored at room temperature or frozen for 10, 17 and 24 days, after the solution was filtered and after it was heated at 56 degrees C.) versus intravenous therapy for the treatment of cytomegalovirus (CMV) retinitis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with cytomegalovirus retinitis. No further details were given.

Setting
Hospital. The study was carried out in Australia.

Dates to which data relate
The main effectiveness data were taken from a single study conducted between 1991 and 1993. No explicit information concerning when resource and cost data were obtained was given. The price year was not stated.

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

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

Study sample
A cohort of 22 patients (35 eyes) was included in the analysis. No further details were given. Power calculations to determine the sample size were not given.

Study design
Case-control study. Patients were treated over the period 1991-93 as outpatients, visiting twice a week for 3 weeks for induction therapy, then weekly for maintenance therapy (total of 613 weeks of therapy). There was no loss to follow-up.
Analysis of effectiveness
Primary health outcomes were the stability and solubility of the ganciclovir solution and the shelf life of the made-up injections.

Effectiveness results
The stability of 20 mg/ml ganciclovir in saline was 20.66, 20.34 and 20.36 at room temperature for 10, 17 and 24 days of storage, respectively. The corresponding figures were 20.41, 20.25 and 20.24 at 5 degrees C., and 20.85, 20.41 and 20.53 at -8 degrees C. The solubility of 20 mg/ml ganciclovir in saline was 19.93 if freshly prepared, 20.21 if freshly prepared and filtered, 20.18 if freshly prepared and heated at 56 degrees C., 20.21 if freshly prepared and filtered and heated, 20.41 if stored at -8 degrees C., and thawed at room temperature and 20.31 if stored at -8 degrees C., and heated at 56 degrees C for 30 minutes.

Clinical conclusions
There was little variation in the concentration of ganciclovir regardless of the storage conditions, suggesting that the 20 mg/ml solution was very stable. The heating and filtering experiments suggest that maximum solubility was achieved both in the freshly prepared and thawed frozen-stored solution.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the analysis and as such the benefits are considered to be the same as the outcome measures.

Direct costs
The costs measured were pharmacy costs as an approximation to staff, depreciation and disposable costs of preparing the injections and the fees for outpatient visits and injection procedure. The quantity/cost boundary adopted was the hospital. Resource quantities were reported separately from the prices. For the intervention, quantities were based on actual data, while costs were estimated using the standard charge for an outpatient visit by the hospital and the Commonwealth Medical Benefits Schedule (MBS). For the comparator, quantities were based on an estimate while unitary costs were obtained from the same sources as before. Discounting was not undertaken. The price year was not stated.

Statistical analysis of costs
Not undertaken.

Currency
Australian dollars (Aus$).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
The stability of 20 mg/ml ganciclovir in saline was 20.66, 20.34 and 20.36 at room temperature for 10, 17 and 24 days of storage, respectively. The corresponding figures were 20.41, 20.25 and 20.24 at 5 degrees C and 20.85, 20.41 and 20.53 at -8 degrees C. The solubility of 20 mg/ml ganciclovir in saline was 19.93 if freshly prepared, 20.21 if freshly prepared and filtered, 20.18 if freshly prepared and heated at 56 degrees C., 20.21 if freshly prepared and filtered and heated, 20.41 if stored at -8 degrees C., and thawed at room temperature and 20.31 if stored at -8 degrees C., and heated at 56 degrees C for 30 minutes.
Cost results
The total cost of intravitreal therapy was Aus$172,435 and the estimate for intravenous treatment was Aus$490,521. This represents a total saving of Aus$318,086 (65% of the comparator's cost) or Aus$14,458 per patient. The saving per patient per year was Aus$29,946.

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

Authors' conclusions
Ganciclovir is remarkably stable as a 20 mg/ml solution. It can be made up as a batch of injections and stored safely for at least 1 month. This allows the efficient use of pharmacy services with little waste from each ampoule of ganciclovir. High dose intravitreal ganciclovir therapy may be administered in a very cost-effective way which, along with its acceptability to patients, safety and clinical efficacy, makes it an attractive method of treatment of CMV retinitis.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear. Apart from superior control of retinitis, this therapy offers advantages in terms of quality of life for the patient and significant cost savings when compared with intravenous therapy. You, as a user of this database, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
Although details of the patient population were not reported, the estimate of measure of benefit used in the economic analysis is likely to be internally valid and the data have not been used selectively.

Validity of estimate of costs
Resource quantities were reported separately from the prices and important cost items do not appear to have been omitted.

Other issues
The authors' conclusions are likely to be justified given the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed. However, appropriate comparisons were made with other studies in relation to complications of intravitreal injections, survival and contralateral diseases. The results do not appear to have been presented selectively. A synthesis of benefits and costs could have been provided which would have increased the validity of the economic evaluation.

Implications of the study
Further research is required in assessing better treatments of CMV retinitis.

Source of funding
None stated.

Bibliographic details

PubMedID
7547787

Indexing Status
Subject indexing assigned by NLM
MeSH
Cytomegalovirus Retinitis /drug therapy; Drug Costs; Drug Stability; Ganciclovir /administration & dosage /chemistry; Humans; Injections; Injections, Intravenous /economics; Vitreous Body

AccessionNumber
21995000953

Date bibliographic record published
31/07/1999

Date abstract record published
31/07/1999