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

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Adult renal transplant recipients.

Setting
Hospital. This study was carried out at the Washington University School of Medicine, St Louis, Missouri, USA.

Dates to which data relate
Effectiveness and resource use data were collected between 12 September 1994 and 21 May 1996. The price year was 1996.

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

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

Study sample
163 adult renal transplant recipients were enrolled, 82 in the Thymoglobulin arm and 81 in the Atgam arm. No power calculations were reported. One patient in the Atgam arm was determined at the end of the study not to have had an acute rejection and was excluded from the analysis of the effectiveness results, but was included in the pharmaco-economic analysis.

Study design
This study was a randomised, double-blind trial carried out at 25 transplant centres in the USA. Patients were followed-up for 90 days following initiation of rejection therapy. No patients were lost to follow-up.
Analysis of effectiveness
The analysis was based on intention to treat. The primary health outcomes included the proportion of patients needing refractory rejection treatment, cytomegalovirus (CMV) treatment or prophylaxis, return to dialysis and post-treatment hospitalisation. At analysis, groups were shown to be comparable in terms of clinical and demographic characteristics.

Effectiveness results
Fewer thymoglobulin-treated patients experienced refractory rejection (16% versus 38%), especially if they received the transplant from an African American donor or a cadaveric donor. Fewer thymoglobulin-treated patients needed CMV treatment or prophylaxis (79% versus 79%), return to dialysis (7% versus 17%), and post-treatment hospitalisation (45% versus 47%). The relative rates of refractory rejection, cytomegalovirus treatment or prophylaxis, return to dialysis, and post-treatment hospitalisation were generally similar, but not identical, in the patient subsets and the set of all patients.

Clinical conclusions
Thymoglobulin for treatment of acute rejection in renal transplantation provides important clinical advantages over treatment with atgam.

Modelling
No modelling was undertaken.

Measure of benefits used in the economic analysis
The primary measure of benefit was the proportion of patients needing refractory rejection treatment.

Direct costs
Costs were not discounted given the short time frame of the study (90 days). Quantities and costs were not reported separately. Direct costs included costs associated with immunosuppression, additional rejection treatment for refractory rejection, CMV treatment, return to dialysis and complications requiring hospitalisation. The quantity/cost boundary was that of the hospital. The estimation of quantities and costs was based on actual data. Costs were adjusted to 1996 US dollars using the medical services component of the consumer price index.

Statistical analysis of costs
Differences in costs were tested by univariate two-tailed analysis of variance.

Indirect Costs
Not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Fewer thymoglobulin-treated patients experienced refractory rejection (16% versus 38%), especially if they received
the transplant from an African American donor or a cadaveric donor.

**Cost results**
Patients treated with thymoglobulin were associated with significantly lower costs of care during the 90 days post-therapy compared to patients treated with atgam (cost difference of $5,277). A significant cost difference (atgam - thymoglobulin) was also found in the following patient subsets: African American donor ($12,509), African American recipient ($8,337), diabetes causing ESRD ($6,581), and cadaveric donor ($7,133). In recipients who had previous transplants, costs of care were similar.

**Synthesis of costs and benefits**
Not reported.

**Authors' conclusions**
Thymoglobulin for treatment of acute rejection in renal transplantation provides important clinical advantages over treatment with atgam. Thymoglobulin is particularly advantageous in transplants from African American and cadaveric donors and African American and diabetic recipients of renal transplants.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. You, as a user of this database, should verify whether these health technologies are relevant to your setting.

**Validity of estimate of measure of benefit**
The measures of benefit seem to be valid. Some of the patient subsets, however, suffered from a small sample size.

**Validity of estimate of costs**
Only direct costs were included. Indirect costs such as productivity losses or costs falling to relatives were not considered but would be relevant if a societal perspective were chosen. No sensitivity analysis was conducted on the cost estimates.

**Other issues**
Given that patients were enrolled from 25 centres, effectiveness and cost differences may reflect specific characteristics of these centres rather than differences in treatment. No comparisons with other relevant studies were made.

**Implications of the study**
The implications for practice suggest that thymoglobulin for treatment of acute rejection in renal transplantation provides important clinical advantages over treatment with atgam. Thymoglobulin is particularly advantageous in transplants from African American and cadaveric donors and African American and diabetic recipients of renal transplants.

**Bibliographic details**

**PubMedID**
10083103
Other publications of related interest
Costs savings associated with thymoglobulin for treatment of acute renal transplant rejection in patient subsets.
Transplantation Proceedings 1999;31(3B Suppl S):7S-8S.

Indexing Status
Subject indexing assigned by NLM

MeSH
African Continental Ancestry Group; Antilymphocyte Serum /economics /therapeutic use; Costs and Cost Analysis;
Demography; Diabetic Nephropathies /surgery; Double-Blind Method; Graft Rejection /drug therapy; Humans;
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