Outcomes and costs of outpatient and inpatient cataract surgery: a randomised clinical trial

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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
Two health technologies were considered in the study: outpatient (ambulatory) and inpatient cataract surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing cataract surgery.

Setting
The setting was the community. The economic study was carried out in Barcelona, Spain.

Dates to which data relate
Effectiveness evidence and resource use data were gathered between April 1993 and November 1996. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was 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 effectiveness analysis.

Study sample
All patients undergoing cataract surgery in the ophthalmology departments of three hospitals in Barcelona from April 1993 to November 1996 participated in the study. Eligibility criteria were as follows:

- patients should have been scheduled for cataract surgery not in combination with other ophthalmologic procedures;
- patients should have sufficient family or social support in the early postoperative period;
- patients should live under 1 hour's travel from the hospital; and
- there should be an absence of severe ocular comorbidity, also in the case of hospital admission.
Patients who could not complete a telephone interview because of severe deafness or a cognitive effect were excluded. Power calculations were performed in the planning phase in order to ensure the study would have an 80% power to detect an absolute difference in complication rates of 5% between the two groups (5% versus 10%, alpha error 0.05). The number of patients required in each group was at least 484. To assess perceived health, however, the number of subject needed to obtain statistical significance was smaller, thus 192 patients in each group were enrolled for subgroup analysis. Of the 1,162 eligible patients, 52 refused to participate and 76 were missed. Therefore 1,034 subjects were divided between the two groups. 464 (89.6%) of the 518 subjects in the outpatient group and 471 (91.3%) of the 516 subjects in the inpatient group completed the trial.

Study design
The study was an unmasked randomised controlled trial, carried out in three hospitals in Barcelona. The randomisation process was generated by simple random number software. Duration of follow-up was 4 months after the intervention. The loss to follow-up was 10.4% in the outpatient group and 8.7% in the inpatient group.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary outcomes were the early (within 24 hours after surgery) and late (between 24 hours and 4 months after surgery) postoperative surgical complications; the visual acuity of the operated and the better eye at 4 months after the surgery; and the change in visual acuity (pre-postoperative). Secondary outcomes were also assessed through telephone interviews administered by trained interviewers in the preoperative and 4-month postoperative periods. These outcomes were visual function (V-14 Index), cataract-related symptoms (Cataract Symptom Score) and overall perceived health status (Sickness Impact Profile). By conducting several statistical analyses, groups were shown to be comparable in terms of baseline characteristics (demographic and clinical features). No statistically significant differences were found among lost patients in the two study groups.

Effectiveness results
Early postoperative complications were more significantly frequent among outpatients. Overall, 64 outpatients (18.8%) had at least one early postoperative complication compared to 43 (9.1%) inpatients (Risk Ratio 1.6, 95% CI: 1.1 - 2.4).

The proportion of outpatients (18.8%) suffering from at least one late postoperative complications was no different from inpatients (18%).

Both groups of patients experienced a similar degree of improvement in visual acuity in the operated eye and in the better eye.

Among the secondary outcomes, only the 4-month postoperative V-14 scores were higher for the outpatient group compared to the inpatient group (92.8 versus 87.6, p=0.03).

Clinical conclusions
Most clinical and perceived clinical outcomes of cataract surgery were similar in the outpatient and inpatient settings. Outpatients had a higher probability of experiencing at least one complication in the first 24 hours after the intervention. However, these complications could be easily treated and the final outcome after 4 months was not affected.

Measure of benefits used in the economic analysis
Clinical outcomes were left disaggregated and no summary benefit measure was used, therefore a cost-consequences analysis was performed.

Direct costs
Discounting was not relevant because costs were incurred over about 4 months. The surgical operation costs included surgeon, nursing and anaesthetist costs according to the time spent in the operating theatre, and the costs of supplies. Inpatient and outpatient hospital stay costs included the average daily cost of the physician and nursing staff. In addition, the pharmacy, laboratory test and radiology costs were calculated per patient. Follow-up costs included the costs of follow-up visits and costs of readmissions due to complications. Quantities and costs were not reported separately. The quantity/cost boundary adopted seems to have been that of the hospital. The estimation of quantities and costs was based on actual data but the source of the data was not clearly stated. Resource use data were gathered between April 1993 and November 1996. The price year was not reported.

**Statistical analysis of costs**
The t-test was carried out to compare the total costs of the two strategies.

**Indirect Costs**
Indirect costs were not included in the analysis.

**Currency**
Euros. 1 Euro =166 Spanish Pesetas.

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
Please refer to the effectiveness results reported earlier.

**Cost results**
The cost of the surgical intervention was 411.2 Euros for outpatients and 388.5 Euros for inpatients. The costs of explorations, drugs, and intraocular lens were 338.5 Euros for inpatients and 358.9 Euros for outpatients and the difference was statistically significant. The cost of a hospital stay was significantly lower for outpatients than for inpatients: 104.1 Euros versus 349.2 Euros, (p<0.001). The costs of follow-up were 147.5 Euros for outpatients and 121.4 Euros for inpatients. Overall, the total costs were 1,001.3 Euros for outpatient surgery and 1,218 for inpatient surgery. The difference was statistically significant (p<0.001).

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

**Authors’ conclusions**
The authors concluded that ambulatory surgery was as effective as inpatient surgery, but it was associated with lower costs, due to the savings in terms of surveillance in the hospital.

**CRD COMMENTARY - Selection of comparators**
The selection of the two health technologies was based on the choice of comparing the two most used alternatives to treating cataracts in Spain. You should consider whether they represent the current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness measures are likely to be valid because of the randomisation process. The effect of confounding
variables was also accounted for in the trial, with the performance of appropriate statistical comparisons among the
groups. In addition, power calculations in the planning phase of the study enhanced the internal validity of the analysis.

Validity of estimate of measure of benefit
Not relevant.

Validity of estimate of costs
As the authors noted, it would have been appropriate to include the indirect costs of the alternative technologies. The
exclusion of indirect costs could have biased the results in favour of the outpatient surgery option. Further, indirect cost
analysis would have permitted the adoption of a societal perspective, which seems appropriate given that the care load
for patients undergoing cataract surgery is often transferred to the family or to other people who care for the patient at
home.

Other issues
The authors made appropriate comparisons of their results with those from other studies. However, the issue of the
generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed.
Therefore the results in terms of effectiveness and costs are likely to be specific to the Spanish setting.

Implications of the study
The main implication of the study concerned the amount of cost-savings associated with outpatient surgery. The authors
estimated that in Spain if 80% of the interventions could be carried out in outpatient settings, it would be possible to
realise annual savings of about 30 million Euros.

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