Extracapsular cataract extraction compared with small incision surgery by phacoemulsification: a randomised trial

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 techniques for cataract extraction were examined. The first approach consisted of extracapsular cataract extraction (ECCE) with insertion of an intraocular lens. This is a procedure that requires a relatively large incision to extract the lens and insert the new one. The second procedure was based on a new technique. This uses a smaller incision and an ultrasonically driven oscillating needle to emulsify the lens (phacoemulsification), combined with an automated irrigation/aspiration system to remove the lens material from the eye (Phako).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients aged at least 40 years who were suffering from age-related cataracts. Patients were excluded from the study if they were unsuitable for Phako, if they needed combined surgical procedures, or if their mobility or social circumstances were thought likely to seriously hinder the required follow-up visits. They were also excluded if they had other eye disorders capable of compromising vision (such as amblyopia, glaucoma, diabetic retinopathy or macular degeneration) or if the axial length of the eye was more than 26.5 mm (pathological high myopia).

Setting
The setting was a hospital. The economic study was carried out in the UK.

Dates to which data relate
No dates relating to the effectiveness and resource use data were reported. The price year was not stated. Note: correspondence with the authors, subsequent to this abstract being written, has indicated that the price year was 1997/98.

Source of effectiveness data
The effectiveness evidence came from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients as that used in the effectiveness study.
Study sample
Preliminary power calculations were performed. These suggested that an overall sample of 440 was required to give at least 90% power (alpha=0.05) to detect a difference between proportions of at least 15% in the primary health outcomes. Thus, the study aimed to randomise a sample of 500 patients to take into account losses to follow-up. Of the 821 patients invited to participate in the two study centres, 630 agreed to be included in the study. However, 130 were not enrolled for a variety of reasons, such as ineligibility, refusal and surgery date problems. Therefore, the study sample comprised 500 patients, of which 249 were in the ECCE group and 251 in the Phako group. However, 13 patients in the ECCE group and 5 in the Phako group did not receive the allotted treatment and a few patients in both groups switched to the other treatment. The final study sample included 232 patients in the ECCE group and 244 patients in the Phako group.

Study design
This was a randomised clinical trial, which was carried out in two centres (the Moorfields Eye Hospital in London and the Oxford Eye Hospital in Oxford). The unit of randomisation was the individual patient, with only one eye considered for cataract surgery. Randomisation was stratified by the surgeon with blocks of size four and six, and was performed using allocation codes in sealed, numbered, opaque envelopes. The patients were followed for one year and the outcomes were assessed at 3 and 6 weeks, 3 and 6 months, and one year after surgery. The loss to follow-up was 21 patients in the ECCE group and 22 patients in the Phako group. Spectacles were given at 3 weeks postoperatively in the Phako group and at 3 months in the ECCE group. The patient and the optometrists carrying out the follow-up assessment were blinded to the treatment assignment, but the optometrists could not be masked to the size and location of the surgical incision, which revealed the type of surgery.

Analysis of effectiveness
The basis of the analysis of the clinical study was intention to treat. Statistical regression analyses were conducted to adjust for possible confounding effects of prognostic factors such as age and gender. The primary health outcomes used in the effectiveness study were:

- the proportion of patients who achieved visual acuity of 6/9 (<0.2 logMAR) or better with and without spectacles;
- the combined outcome of visual acuity (6/9 or better) and refraction (within plus or minus 1 dioptre of the planned refraction);
- capsule rupture and/or vitreous loss as a complication during surgery; and
- the incidence of capsule opacity during the first year after surgery.

Minor complications and several secondary outcomes were also evaluated. At baseline, prognostic factors were balanced in the two study groups, which were then comparable.

Effectiveness results
Without spectacles, the proportions of patients who achieved good visual acuity in the ECCE and Phako groups were 11% and 33% at 3 weeks, (p<0.001), 15% and 36% at 6 weeks, (p<0.001), 19% and 35% at 3 months, (p<0.001), 21% and 38% at 6 months, (p<0.001), and 20% and 39% at 12 months, (p<0.001). With spectacles, the corresponding values were 68% and 87% at 3 weeks, (p<0.001), 78% and 90% at 6 weeks, (p=0.001), 80% and 93% at 3 months, (p<0.001), 86% and 92% at 6 months, (p=0.046), and 86% and 91% at 12 months.

The combined outcome of good visual acuity and refraction in the ECCE and Phako groups was reached in 51% and 67% of the patients at 3 weeks, (p<0.001), 57% and 69% at 6 weeks, (p=0.007), 60% and 69% at 3 months, (p=0.050), 65% and 67% at 6 months, (p=0.553), and 65% and 69% at 12 months, (p=0.361).

The incidence of capsule opacity during the first year after surgery was 29% in the ECCE group and 20% in the Phako group, (p=0.014).
Other events during the follow-up period were similar in the two study groups.

Capsule rupture and/or vitreous loss occurred in 9 patients (4%) in the ECCE group and in 8 patients (3%) in the Phako group, \( p=0.808 \).

The proportion of patients who reported no surgical complications was 80% in the ECCE group and 93% in the Phako group, \( p<0.0001 \).

**Clinical conclusions**
The effectiveness study showed that the patients in the Phako group had better visual acuity after surgery and fewer complications than those who underwent ECCE.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore conducted.

**Direct costs**
Discounting was not relevant since the costs per patient were incurred during one year. However, a 6% depreciation rate, according to a NHS agreement for theatre and equipment investment, was incorporated and discounting was performed. The unit costs were reported separately from the quantities of resources used. The health services included in the economic evaluation were staffing, capital charges, overheads, capital equipment, disposables and intraocular lenses, drugs and spectacles. The cost/resource boundary adopted in the study was that of the UK NHS, although some costs relevant to the patient were also included in the economic evaluation. The estimation of resource use was evaluated alongside the clinical study. The costs were estimated using data derived from the two study centres, although the equipment costs from a third independent comparator centre were substituted for costs evaluated in the Moorfields centre, which were atypically low. No price year was reported. Note: correspondence with the authors, subsequent to this abstract being written, has indicated that the price year was 1997/98.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not included.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
A sensitivity analysis was conducted to take into account the variation in the most costly input. The type of analysis was not reported.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs per procedure were 367.57 in the ECCE group and 359.89 in the Phako group. The cost-savings
associated with Phako were modest in the sensitivity analysis.

**Synthesis of costs and benefits**
Not relevant as a cost-consequences analysis was carried out.

**Authors’ conclusions**
At the one-year follow-up, the phacoemulsification-based treatment (Phako) for cataract extraction was slightly more effective than extracapsular cataract extraction (ECCE). In addition, it was associated with lower costs, mainly due to the smaller proportion of patients requiring distant spectacles.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The authors stated that ECCE represented the most widely used procedure for cataract extraction from 1982 until recently, while Phako constituted a more advanced approach. You should decide whether they represent widely used interventions in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of the effectiveness used a randomised clinical trial, which was appropriate for the study question. The setting of the study was reported, as well as the method of randomisation. The study sample appears to have been representative of the study population. A blind assessment of the outcomes was difficult to achieve due to objective reasons, but was partially performed. The basis of the analysis of the clinical study was intention to treat. The internal validity of the analysis was further enhanced by the performance of preliminary power calculations, which took into account potential loss to follow-up. Also, statistical analyses to evaluate the impact of prognostic factors on the estimated outcome. The authors acknowledged that patient loss to follow-up could have represented a limitation of the analysis. The "surgeon effect" appears to have been negligible.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
The perspective adopted in the study was reported and some costs relevant to the patients were also included. The unit costs were appropriately reported separately from the quantities of resources used. The costs were treated deterministically in the base-case, but some sensitivity analyses were conducted to take into account the variability in cost data. The source of the cost data was reported. Resource consumption was estimated alongside the clinical trial. Equipment depreciation was considered. The travel expenses for the patients could not be reliably evaluated.

**Other issues**
The authors stated that their findings were similar to those of a national survey of cataract surgery practice. The issue of the generalisability of the study results to other settings was not addressed. In addition, the overall external validity of the analysis was low, although many details concerning the economic side of the analysis were reported, thus enhancing the reproducibility of the study. The study referred to patients undergoing cataract extraction surgery and this was reflected in the conclusions of the analysis.

**Implications of the study**
The study revealed that a new technique for cataract extraction consisting of a smaller incision and subsequent use of phacoemulsification (Phako) was effective in terms of visual acuity and led to cost-savings in comparison with the standard ECCE approach. The authors noted that there is room for improvements in the organisation of the procedure.
which could result in further efficiency.

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