The clinical effectiveness and cost-effectiveness of second-eye cataract surgery: a systematic review and economic evaluation

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Scientific summary

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Background

Elective cataract surgery is the most commonly performed surgical procedure in the NHS. In bilateral cataracts, the eye with greatest vision impairment as a result of a cataract is operated on first. Depending on how severe the cataract is, cataract surgery in the first eye can substantially improve a person's vision and quality of life. However, it is unclear from existing studies whether or not second-eye surgery provides enough incremental benefit to patients to be considered clinically effective and cost-effective, particularly as the clinical criteria which have been used for determining eligibility of patients for cataract surgery have become less stringent in recent years. Also, it is unclear at what degree of visual impairment (or impairment of quality of life) it would be appropriate to recommend second-eye surgery.

Objectives

This health technology assessment aims to assess the clinical effectiveness and cost-effectiveness of second-eye cataract surgery. Specific objectives were:

- to conduct a systematic review of studies assessing the clinical effectiveness of second-eye cataract surgery
- to conduct an economic evaluation comprising:
    - a systematic review of cost-effectiveness studies of second-eye cataract surgery
    - a systematic review of studies of health-related quality of life (HRQoL) in people who have had cataract surgery
    - an economic model, developed de novo or adapted from an existing one, to estimate cost-effectiveness of second-eye cataract surgery.

Methods

Systematic reviews of clinical effectiveness, cost-effectiveness and health-related quality of life

Inclusion criteria for the systematic review of clinical effectiveness were:

- Population: adults aged 18 years and above who have had one cataract operation already and still have or develop significant cataract-related visual impairment in the other eye.
- Interventions: cataract surgery for the second eye (any surgical technique).
- Comparators: cataract surgery in one eye only (with additional supportive care if this is usual practice, such as prescription glasses).
- Outcomes: any measures of clinical vision (including measures of visual acuity, contrast sensitivity and stereopsis); any patient-reported measures of visual disability and symptoms; patient satisfaction with surgery and vision; HRQoL [e.g. European Quality of Life-5 Dimensions (EQ-5D) health survey]; adverse events.
- Types of studies: randomised controlled trials (RCTs). If necessary, non-RCT data were sought to inform the cost-effectiveness analysis (e.g. on safety).

The systematic reviews of cost-effectiveness and HRQoL employed the inclusion criteria listed above with the following exceptions:

- Studies of any design were eligible for the cost-effectiveness review if they reported full economic evaluations (e.g. cost-effectiveness, cost–utility).
- Studies of any design were eligible for the systematic review of HRQoL if they used generic preference-based HRQoL measures or generic preference valuation methods, and reported health utility values.

Twelve electronic bibliographic databases were searched in March–April 2013 using sensitive search strategies developed and refined by an experienced information specialist. The databases included MEDLINE, EMBASE, Web of Science, The Cochrane Library and the Centre for Reviews and Dissemination. Relevant internet pages were also searched. Reference lists of included studies and of other relevant publications were checked and experts contacted.

Retrieved references were screened for relevance against the inclusion criteria by two independent reviewers using a standardised study selection worksheet. Studies that met all the inclusion criteria were included in the systematic review. Data were extracted from the included studies by one reviewer using a standard data extraction template and were checked by a second reviewer. The quality of the included studies was assessed independently by two reviewers using the Cochrane Collaboration risk of bias criteria for RCTs of clinical effectiveness and standardised checklists for studies of cost-effectiveness and HRQoL. Data from the included studies were synthesised narratively.

Economic evaluation

An economic model was developed to estimate the cost-effectiveness of second-eye surgery in patients with bilateral cataracts, compared with cataract surgery in one eye only (i.e. only first-eye surgery). In the model, second-eye cataract surgery is associated with a change in visual acuity and a corresponding change in HRQoL, assumed to last the patient's lifetime. Patients undergoing surgery may or may not experience post-surgical complications. Post-surgical complications and consequences are associated with a health disutility and require additional treatment.

The model evaluates costs (in UK pounds using a 2012 price base) from the perspective of the NHS and the impact of including Personal Social Services costs is explored. Outcomes in the model are expressed as quality-adjusted life-years (QALYs), and cost-effectiveness is expressed in terms of incremental cost-effectiveness ratios (ICERs). Uncertainty with regard to model input parameters was investigated through deterministic and probabilistic sensitivity analyses, and scenario analyses. Both costs and outcomes were discounted using a 3.5% annual discount rate, in line with current guidance.

Results

Systematic review of clinical effectiveness

In total, 993 potentially relevant references were identified, of which 12 full-text papers were retrieved and three papers describing three RCTs, conducted between 1994 and 2004, met the inclusion criteria. Two RCTs were conducted in the UK and one in Spain. Participants were elderly people (mean age 71.1–79.9 years) with bilateral cataracts. One RCT included only women, whereas the others also included men. All were two-arm, parallel-group RCTs which compared patients expedited to receive second-eye cataract surgery within a specified target period (intervention group) and patients who were scheduled for second-eye surgery at the end of the study according to routine clinical practice (waiting list comparator group). The target time for second-eye surgery in the intervention group was 4–6 weeks after randomisation (two RCTs) or 2–4 months after first-eye surgery (one RCT). The number of participants randomised ranged from 208 to 296.

Owing to the type of surgical intervention under consideration, none of the RCTs were able to mask participants to the allocation group. One RCT was additionally considered at high risk of detection bias as outcome assessors were not masked, whereas another RCT was judged to be at high risk of reporting bias as a result of evidence of selective reporting of outcomes. Judgements of low risk of bias could be made with confidence only for selection bias (random sequence generation: one RCT; allocation concealment: two RCTs); other domains of bias were judged to be unclear.

Outcomes were measured 4–12 months after the intervention group had received second-eye surgery. The RCTs differed in their study characteristics, which precluded the pooling of any outcomes across the RCTs in a meta-analysis.

All three RCTs reported measures of visual acuity, contrast sensitivity and stereopsis. Many participants in all three RCTs already had good binocular visual acuity and contrast sensitivity before second-eye cataract surgery. Binocular visual acuity and contrast sensitivity were statistically significantly better after second-eye cataract surgery in three and two RCTs, respectively, but differences were small and appear to be of limited clinical importance. In contrast, patients' stereopsis at baseline varied among the RCTs, with 61–71% having no functional stereopsis in one RCT. Statistically and clinically significant improvements in stereopsis occurred after second-eye surgery in all three RCTs, with the most substantial improvement being in the RCT whose patients had the worst baseline stereopsis.

Patient-reported outcomes for HRQoL and psychological well-being were measured using generic health status instruments in three RCTs [EQ-5D, short form questionnaire 12- and 36-item health survey instruments (SF-12 and SF-36, respectively)], with instruments that assessed specific HRQoL domains in one RCT (activities of daily living, anxiety, depression, falls efficacy and handicap), and with an instrument that specifically assessed visual functional disability [Visual Function Index-14 (VF-14)] in two RCTs. Among these measures, clinically meaningful improvements after second-eye cataract surgery were demonstrated on only one outcome in one RCT (the mental health component score of the SF-12). This finding may reflect limitations of some of the instruments employed.

Falls and fractures in elderly women were assessed as outcomes in one RCT. Compared with first-eye cataract surgery, second-eye surgery did not reduce the number of falls or fractures significantly.

Only two RCTs provided information on surgical complications, but it is unclear how completely they were reported, and some longer-term complications may have been missed by the relatively short follow-up (6 or 12 months after surgery).

Systematic review of cost-effectiveness

A total of 190 potentially relevant references were identified by the cost-effectiveness searches. Of these, the full texts of five papers were retrieved and four papers describing three studies published between 2003 and 2010 met the inclusion criteria. One of the studies was conducted in the UK, one in the USA and the other in Finland. All three were cost–utility studies comparing second-eye cataract surgery with no second-eye surgery. One study was a modelling study, one was a trial-based economic analysis and the third was a prospective HRQoL study. Each of the studies based the effectiveness of the intervention on a single trial or study, rather than a systematic review. Only one study modelled the costs of treating complications.

There was variation between studies in the degree of pre-surgical visual impairment in the second eye. In two studies the mean pre-surgical visual acuity was 0.24 (decimal, equivalent to around 6/24 metres), whereas in the other study 86% of participants were described as having good vision in the eye to be operated on (6/12 or better). Each study used a different HRQoL instrument [EQ-5D, time trade-off (TTO) and 15D]. Post-surgical changes in HRQoL varied between the studies, with a utility gain of 0.109 in one study and a utility loss of 0.01 in two studies.

Cost-effectiveness results varied across the studies. One study reported an ICER of US$2495, and another reported an ICER of £44,263. However, in the latter study the ICER reduced to £17,299 when a lifetime horizon was used. The third study did not report an ICER as second-eye cataract surgery was associated with negative QALYs.

In summary, there was variability across the three studies in terms of modelling approach, patient characteristics and results, though second-eye cataract surgery would be considered cost-effective under currently employed willingness-to-pay thresholds if a lifetime horizon is used. However, these economic evaluations had various limitations, indicating a need to develop a de novo economic model to assess cost-effectiveness of second-eye cataract surgery in the NHS.

Systematic review of health-related quality of life

Literature searching identified a total of 860 references, of which 10 studies, reported in a total 11 publications, were included in the review. The included studies were diverse in terms of aims, comparisons made, study designs, patient characteristics and locations. In the majority of the studies in which baseline clinical vision status was reported, the patients could be classed as having poor visual acuity. A range of HRQoL instruments were used by the studies, the most common being the EQ-5D. Other instruments used included the Health Utilities Index 3 (HUI-3) and TTO method. In four studies, a comparison between first- and second-eye cataract surgery was possible. The utility changes observed varied from negative to positive among the studies, but the more robust studies indicated net utility gains after second-eye surgery.

Economic evaluation

In the base case analysis, second-eye cataract surgery generated 0.68 incremental QALYs at an additional cost of £1341 compared with cataract surgery in one eye only. The ICER was £1964. In the probabilistic analysis, the mean ICER was £1970 and the probability that second-eye cataract surgery would be cost-effective at willingness-to-pay thresholds of £10,000 and £20,000, respectively, was 100%. The base case results did not change significantly when input parameters and assumptions were varied in deterministic sensitivity analyses and scenario analyses. Notable exceptions were the utility change associated with second-eye surgery where ICERs ranged between −£2908 and £5734 per QALY in scenario analyses that included utility estimates less favourable than the base case.

Discussion

This health technology assessment used standard rigorous methods for evidence synthesis and economic decision modelling. Evidence for clinical effectiveness, cost-effectiveness and HRQoL improvement was systematically sought and appraised and synthesised. The economic model was informed by previously published models, and their limitations were taken into account where possible. Experts in ophthalmology and patient care have been consulted for input throughout the review.

Limitations include the relatively small evidence base (three published RCTs and three published economic evaluations), suboptimal reporting of studies and heterogeneity of study characteristics, precluding quantitative meta-analysis. As is common in many economic evaluations, certain assumptions have been made regarding resources, costs, surgical complications, patient characteristics and outcomes. These have all been explicitly reported and tested in sensitivity and scenario analysis.

Conclusions

Second-eye cataract surgery was associated with clinically meaningful improvement in stereopsis and, in one RCT, in the mental health component of HRQoL. Most other measures of clinical vision, HRQoL and vision-related functional ability did not change to a clinically important degree from before to after second-eye surgery. However, changes in quality of life and vision-related functional ability were assessed using instruments with known limitations and patients in the RCTs already had relatively good vision and HRQoL after first-eye surgery. Based on economic modelling using the best available evidence, second-eye surgery would be considered generally cost-effective under conventional willingness-to-pay thresholds used in the NHS. The results were robust to a range of scenarios and assumptions but appear to be sensitive to utility values chosen from published studies, meaning that second-eye surgery was not cost-effective in at least one scenario analysis.

To overcome evidence limitations, there is a need to develop improved quality-of-life assessment tools for patients with visual impairments that are capable of detecting clinically important effects of changes in vision on quality of life and functional ability. To fully capture the effects of bilateral cataracts and second-eye cataract surgery on patients' clinical vision, HRQoL and visual disability, a 'core' set of outcome measures may be appropriate, including tests of vision which may be more sensitive than binocular visual acuity (e.g. including stereopsis and glare disability) as well as patient-reported functional disability outcome(s). However, compared with the assessment of visual acuity, testing patients' stereopsis would likely incur additional costs associated with test equipment and staff training.

A well-designed RCT, using a representative UK patient population sample stratified by cataract severity (or by another indicator of cataract-related visual function), and including a planned cost-effectiveness evaluation based on methods for estimating utility changes (e.g. the TTO), would help to confirm the clinical effectiveness and cost-effectiveness of second-eye cataract surgery under current NHS practice.

Study registration

This project is registered in the PROSPERO database, reference CRD42013004211.

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