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Falls and health status in elderly women following first eye cataract surgery: an economic evaluation conducted alongside a randomised controlled trial

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ABSTRACT

Aim: To evaluate the cost-effectiveness of first-eye cataract surgery compared to no surgery from a Health Service and Personal Social Services perspective.

Methods: An economic evaluation undertaken alongside a randomised controlled trial of first-eye cataract surgery in secondary care ophthalmology clinics. 306 women over 70 years old with bilateral cataracts were randomised to cataract surgery (expedited, approximately 4 weeks) or control (routine, 12 months wait). 75% of participants had baseline acuity of 6/12 or better. Outcomes included falls and the EuroQol EQ-5D.

Results: The operated group cost a mean £2,004 (bootstrapped) more than the control group over one year (95% confidence interval £1,363 to £2,833, $p < 0.001$), but experienced on average 0.456 fewer falls, an incremental cost per fall prevented of £4,390. The bootstrapped mean gain in Quality Adjusted Life Years (QALYs) per patient was 0.056 (95% confidence interval 0.006 to 0.108, $p < 0.001$). The incremental cost utility ratio was £35,704, above the currently accepted UK threshold level of willingness to pay per QALY of £30,000. However, in an analysis modelling costs and benefits over patients' expected lifetime, the incremental cost per QALY was £13,172, under conservative assumptions.

Conclusions: First-eye cataract surgery, whilst cost-ineffective over the trial period, was probably cost-effective over participants' remaining lifetime.

INTRODUCTION

Health care interventions should be effective, affordable, and of sufficient priority over competing calls on limited resources.

Health economic evaluation aims to quantify the incremental costs and benefits of an intervention compared to an appropriate comparator, in order to establish whether the intervention offers value for money. Ideally health benefits are measured on a common generic scale, usually using 'utilities', measuring health-related quality of life (HRQL) on a scale of 0 (death) to 1 (perfect health). HRQL is then combined with length of life changes to estimate the difference in Quality Adjusted Life Years (QALYs) between the interventions being compared. This enables direct comparison with diverse other health interventions.¹ A variety of instruments has been developed to measure HRQL.²⁻⁴ The UK's National Institute of Health and Clinical Effectiveness (NICE) prefers outcomes to be measured using this approach.⁵

The prevalence of cataract is very high amongst elderly people (20% unoperated at age 70, rising to 50% in over 80s).⁶ Surgery for cataract is common, but substantial unmet need remains in the population.⁷ The UK government has committed the National Health Service (NHS) to providing rapid access to surgery for anyone deemed to require it by their clinician.⁸ The sight-restoring effects of surgery in patients with severe bilateral cataract are self-evident. However, there has been a very significant trend over the last two decades to performing cataract surgery at an increasingly earlier stage with a rising proportion having 6/12 vision or better at the time of listing.^{9, 10} The cost-effectiveness of surgery in these patients is open to question.

We previously demonstrated benefits from first eye surgery in a randomised controlled trial (with 'waiting list' controls), in terms of gains in visual acuity, contrast sensitivity, stereopsis, activity, anxiety, depression, confidence, visual disability and handicap and reduced rate of falls and fractures.¹¹

In this paper we present an economic evaluation of first-eye surgery compared to no surgery ever, both in terms of cost-effectiveness and cost-utility, from an NHS and personal social services perspective. Carers' costs are presented separately.

MATERIALS AND METHODS

Participants and randomisation

Participants were women over 70 years of age, with bilateral unoperated cataract, referred to secondary care, who were suitable for phacoemulsification. Exclusions included severe visual impairment or co-morbid eye disease, and memory problems preventing the completion of questionnaires. Ethical committee approval was granted, and participants gave informed, written, consent.

Participants were randomised to immediate first-eye cataract surgery (median 27 days), or no surgery ('waiting list' controls, who had surgery after 9 to 13 months, median 337 days). Only one eye was operated upon. All had refraction. The primary clinical end-point was rate of falling, and the trial was powered to detect a one-third reduction in rate of falling.¹¹

Resource use and costing

All contacts with health and social services, including care home admissions, use of informal care, equipment provided and home modifications (table 1) were collected at an individual patient level from diaries ascertained at 3 and 9 months via telephone interviews, and at 6 and 12 months in face-to-face interviews. Equipment and modifications were assumed to have been paid for by social services with unit costs from the Personal Social Services Research Unit, where available¹², and from internet mobility store price catalogues. In addition, we measured the time costs of informal carers using the human capital approach, applying average net weekly earnings (table 1). Carer costs are excluded from the base case analysis because of controversy surrounding the methods used to value time¹⁵, but are included separately in line with the approach taken by NICE.⁵ All costs in this paper are presented in 2004 pounds sterling (inflated using the Hospital and Community Health Services inflation index¹² where necessary).

<<Insert table 1>>

Outcomes

Patient utility was estimated using the EQ-5D [www.euroqol.org], which has five dimensions (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression), each rated at one of three levels (none, some, severe problems).² When combined these create 243 possible health states, each of which has an empirically-measured utility score assigned (using the time-trade off technique¹⁶)¹⁷. The EQ-5D was administered at baseline and 6 months, and used to construct patient-specific utility paths. In the base case it was assumed the 6-month value would apply one month after surgery (since the benefits of surgery are rapid) and remained constant over a further 11 months.

The number of QALYs for the 12 month trial period was estimated for each patient using area under the curve analysis taking account of baseline. The overall difference in mean QALYs between surgery and no surgery was calculated. Costs and benefits were not discounted in the base case since the trial period was a single year.

Modelling longer term cost utility

The benefits of cataract operations are life long¹⁸, so a long-term analysis was conducted using UK Government life tables to estimate lifetime costs and benefits for each participant where life expectancy was based on their own age and gender.¹⁹ Annual costs for the control group were assumed to remain the same in subsequent years as that observed in the trial period. For the intervention group costs over the final three quarters of the year only were rescaled to reflect a full year, since costs in the first quarter of the year were significantly higher compared to each subsequent quarter ($p < 0.001$) and are

therefore unlikely to reflect future resource use. The rescaled total annual cost was assumed to remain constant over the remaining lifespan. Utility was assumed to remain constant over the remaining lifetime for both groups (a conservative assumption since without the operation vision deteriorates over time).^{11, 20-22} Both costs and benefits were discounted in the lifetime analysis using a rate of 3.5% per annum.^{5, 23}

Statistical analysis

18 patients (5.9%) did not complete the 6-month EQ-5D questions and were excluded. Patients with missing resource use data at one or more time points (death between data collection points, n=2, and early withdrawal, n=19) were imputed using the last observed value carried forward approach and apportioned for the appropriate period. Ten participants who had early non-trial surgery were analysed using intention to treat.

Non-parametric bootstrap analysis using the percentile method confidence interval was undertaken.²⁴ The resulting incremental cost and QALYs were used to generate an incremental cost effectiveness ratio.

Cost Effectiveness Acceptability Curves (CEAC)²⁵, which plot the probability of an intervention being cost-effective compared to an alternative for different levels of willingness to pay (WTP) per QALY, were drawn.

Sensitivity analysis

Sensitivity analyses were performed to test the robustness of both the short and longer term results. Costs in the operated group were skewed by a few very high cost patients. The top 2% and then top 5% of patients were removed. We undertook threshold analysis to find the price of cataract surgery (the single largest unit cost) which would make it cost effective. We varied the assumption about time course of gain in quality of life after operation (immediate and gradual over six months). Finally, in the longer term modelling we tested the impact of varying the discount rate from the 3.5% assumed in the base case to 0%, 3% and 5% as recommended.¹

RESULTS

Data from 288 participants (148 intervention and 140 control) were included in the economic analysis. Baseline visual acuity was 6/12 or better in 75%. Mean corrected acuity was 0.28 log MAR, equivalent to about Snellen 6/11.4.

Resource use and costs

Overall service use was higher in the operated group in the year after randomisation, particularly in the first 3 months after surgery (3.6 times higher, p<0.001). Costs over months 4-12 were not statistically significantly different between groups. There were some potentially important baseline imbalances in reported prior resource use (in the month prior to randomisation), although baseline EuroQol was similar (p=0.9). For example, there were 4 care home residents in the operated group compared with only one

in the control group. The greatest resource use and cost was for hospital outpatient visits (mainly non-ophthalmic) (see table 2 and 3).

The bootstrapped mean total cost per patient (excluding carer time costs) in the operated group was £3,250 (SD 352) compared to £1,247 (SD 120) in the control group (difference £2,004, 95% confidence interval £1,363 to £2,833, $p<0.001$). Total secondary care costs (£2,313 vs. £881, $P<0.001$) and total personal social services costs (£791 vs. £231, $p=0.033$) were also higher in the operated group. There was no difference for primary care costs (£146 vs. £137, $p=0.515$) or carer time costs (£453 vs. £620, $p=0.310$). None of the patients in the control group incurred total costs over £7,421 during the trial year. However, 7 operated participants incurred total costs over £10,700, with three over £21,000. Two of these three high cost users died.

<<Insert table 2>>

<<Insert table 3>>

Cost effectiveness

The bootstrapped mean number of falls per patient in the base case was 0.934 (SD 0.122) for operated participants and 1.390 (SD 0.296) for the control group (difference -0.456, 95% confidence interval -1.153 to -0.083, $p<0.001$). The incremental cost per fall prevented was £4,390 without carer costs and £3,983 with carer costs included.

Cost utility results without carer time costs included

The bootstrapped mean difference in QALYs per patient in the base case was 0.056 (95% confidence interval 0.006 to 0.108, $p<0.001$). The incremental cost effectiveness ratio for surgery in the base case was £35,704. Figure 1 shows the CEAC for the first year after surgery. At a WTP of £30,000 per QALY there is a 35.6% chance of cataract surgery being cost-effective in this population.

<<Insert figure 1>>

Cost utility results with carer time costs included

Surgery remained more costly than control (£3,684 vs. £1,866, $p<0.001$), although the mean bootstrapped cost difference (£1,818; 95% confidence interval £1,057 to £2,639, $P<0.001$) was lower. Incremental cost effectiveness with carer's time cost incorporated was £32,391.

Modelling longer term cost utility

Extrapolating beyond the trial period to assume a time frame for analysis over expected remaining lifetime revealed a mean total bootstrapped cost per patient of £17,933 (SD 2722) operated, compared with £10,725 (SD 1147) control, mean difference of £7,208 (95% confidence interval £1,720 to £13,654, $p<0.001$). The mean difference in QALYs per patient was 0.547 (95% confidence interval 0.084 to 0.963,

$p < 0.001$), with a long-term incremental cost effectiveness ratio of £13,172 when a public sector perspective was taken, and assuming that the utility remained constant in the control group. (In fact, in the 6-month trial period alone utility in the control group deteriorated from 0.70 to 0.67). The long term incremental cost effectiveness ratio was £10,382 when carer costs were included (table 4). Figure 2 shows the CEAC for the longer term model. At a WTP of £30,000 per QALY there is a 90.4% chance of cataract surgery being cost-effective in this population.

<<Insert table 4>>

<<Insert figure 2>>

Sensitivity analysis

The incremental cost utility ratios for various assumptions and sensitivity analyses are given in table 4. Excluding the 2% (3 participants) who had total costs in excess of £20,000 per annum gave an incremental cost effectiveness ratio of £27,205 for the trial period. When the 5% (7 participants) incurring total costs above £10,000 per annum were excluded, the incremental cost effectiveness ratio was £18,170 for the trial period. The unit cost threshold for the cataract operation itself, at which the ICER fell beneath £30,000 was £329 (49% of the actual cost) for the trial period analysis. Changing the assumptions about the time course of improvement after surgery had little effect on conclusions in the trial period or longer term analysis. Using different discount rates in the longer term modelling did not change the ICER significantly. 90% confidence boxes around the mean point estimates of incremental costs and benefits were also drawn. These, together with the results using different discount rates, can be obtained from the corresponding author.

DISCUSSION

First eye cataract surgery is associated with gains in visual function, visual disability, activity, anxiety and depression, confidence, handicap and quality of life.¹¹ But it also had an associated cost, and the relative cost per unit of gain can be calculated to compare this with other interventions.

We found a cost per QALY gained of £35,704 for costs and benefits measured within a year of randomisation falling to £13,172 when costs and benefits were estimated over anticipated remaining lifespan (10 years for a 78 year old woman, the median age) discounting future costs and benefits at 3.5%, and assuming that HRQL does not deteriorate further for someone with an unoperated cataract. Thus in reality, the cost per QALY should be less than this. Currently the upper threshold for implementing interventions in the UK NHS is £30,000 per QALY.^{5, 26} Compared to other health care interventions, first eye cataract surgery for this population seems favourable over the longer term.²⁸

One other study has reported a cost-effectiveness analysis of first-eye cataract surgery alongside a randomised trial for a subgroup of patients predicted to have less than

a 30% probability of gaining improvements in visual function after surgery.²⁹ They found that first eye surgery, compared to watchful waiting, was cost-effective. There are just five other cost utility analyses, mostly short-term and from non-randomised studies, evaluating first eye surgery in broader populations worldwide. These have been incorporated into a meta analysis, which reports a wide range of costs per QALY (US \$1000 to \$22,000, 2004). The key factor affecting cost-utility was the assumed duration of the benefit, for which the authors argue the most valid period is the patient's lifespan.¹⁸

The main strength of the current study was that it was a pre-planned analysis, using data from the perspectives of both formal health and social care, and informal carers, embedded in a randomised controlled trial.

The main caution is that some of our cost data were unexpected. Overall service use was considerably higher in the operated group in the year after randomisation, particularly in the first 3 months post surgery. There were some potentially important baseline imbalances in reported resource use in the month prior to randomisation, most likely due to chance. A further explanation would be a raising of awareness and assertiveness towards available services. There was nothing to suggest from our informal observations that the excess service use was directly related to the cataract surgery. We have not been able to investigate this further. A lot of the excess costs were concentrated in a few participants, who had co-morbid illnesses, spent time in hospital, and in some cases died. The sensitivity analysis in which these outliers were excluded gave a (within year) ICER of £18,170 and a whole life ICER of £1,741 when the top 5% of high users were excluded. These figures may be more generalisable.

Our main analysis was of cost-effectiveness over the year of follow up for which we had real data, but in reality the assumption that cataract surgery is done only for the benefits observed over the subsequent 12 months is invalid - the benefits are life long. Our long term model based on extrapolated data is hypothetical, and, therefore, the results are indicative rather than definitive. Moreover, we assumed a comparator of no surgery ever. In reality many in the control group eventually have surgery, but our assumption allows us to estimate the 'absolute' cost-effectiveness of the procedure. Given the considerable unmet need for surgery in the UK, many people with cataracts currently die before reaching operation.⁷

A large proportion of participants in this trial had minimally visually-impairing cataract. Three quarters had acuity better than the driving standard (Snellen 6/12). This is an important group to study because they are numerous, are common in routine ophthalmology practice, and because it is this group (rather than those on the verge of blindness) in whom the priority given to surgery is open to question. Our study suggests that first eye cataract surgery for this group is likely to be cost effective, especially if a life-long time frame is considered.

Contributors

Tracey Sach performed the economic analyses and drafted the paper. Alex Foss, Tash Masud and Rowan Harwood designed the study. Fran Osborn collected the data and managed the project. Alex Foss, Richard Gregson and Anwar Zaman recruited patients and performed surgery. All authors contributed to and approved the final text. Tracey Sach and Rowan Harwood are guarantors.

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Competing interests

All authors declare that the answers to the questions on your competing interest form [<http://bmj.com/cgi/content/full/317/7154/291/DC1>] are all No and therefore have nothing to declare.

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TABLE 1: Base case unit costs in 2004 pounds sterling

Resource Item	Unit cost†	Source
Primary health care		
GP (Per surgery consultation lasting 9.36 minutes)	£21	PSSRU ¹²
Practice nurse/district nurse (per consultation)	£9	PSSRU
Secondary health care		
A&E (per visit)	£83	PSSRU
Outpatients first visit (geriatric medicine)	£222	DH ¹³
Outpatients follow up visit (geriatric medicine)	£125	DH
Cost per bed day for elderly patients	£166	PSSRU
Cataract operation	£672	DH
Lower limb fractures (day case)	£777	DH
Upper limb fractures (day case)	£858	DH
Personal social services		
Local authority home care worker (per visit)	£12	PSSRU
Day centre visits (per visit)	£29	PSSRU
Short term residential care (per day)	£56	PSSRU
Long term residential care (per day)	£53	PSSRU
Short term nursing home (per day)	£73	PSSRU
Long term nursing home (per day)	£75	PSSRU
Meals on wheels (per meal)	£2.60	Wiltshire foods
Special equipment (per item) (items ranged from long handled sponge to electric buggy)	£4.10 to £499	Varied (available from author)
Patient and carer		
Independently provided home care (per visit)	£10	
Average net weekly earnings (all ages, excluding overtime and minus 35% for income tax, NI and pension)	£320.95	PSSRU NES† ¹⁴

† New Earnings survey 2003, inflated to 2004 wage rates using earnings inflation rate of 0.045.

TABLE 2: Mean (Standard Deviation) resource use and mean difference in resource use per patient (95% Confidence Interval) over the 12 months for first eye cataract surgery and no cataract surgery

Resource use item	Surgery (n=148)	No surgery (n=140)	Mean difference (95% CI)
Secondary health care			
Cataract Operation (per op)	1 (0.00)	0.11 (0.31)	0.89 (0.84 to 0.95)
Outpatients first and follow-up visit (number)	5.99 (4.28)	2.79 (3.91)	3.20 (2.25 to 4.15)
Bed days (number)	3.13 (10.20)	1.16 (3.22)	1.96 (0.22 to 3.71)
A&E (number of visits)	0.39 (0.85)	0.12 (0.37)	0.26 (0.11 to 0.42)

Lower limb fractures (number)	0.01 (0.08)	0.01 (0.08)	0.00 (-0.02 to 0.02)
Upper limb fractures (number)	0.02 (0.14)	0.09 (0.36)	-0.07 (-0.14 to -0.01)
Primary health care			
GP (number of visits)	4.72 (3.79)	5.04 (4.96)	-0.33 (-1.36 to 0.70)
Practice/district nurse (number of visits)	5.22 (9.97)	3.40 (3.59)	1.82 (0.09 to 3.54)
Personal social services			
LA home care worker (number of hours)	12.29 (40.13)	9.39 (31.45)	2.90 (-5.46 to 11.23)
Day centre visits (number of days)	0.13 (0.62)	0.11 (0.74)	0.01 (-0.14 to 0.17)
Residential care (number of days)	9.67 (54.16)	0.50 (3.51)	9.17 (0.35 to 17.99)
Nursing home care (number of days)	0.00 (0.00)	0.14 (1.26)	-0.14 (-0.35 to 0.07)
Meals on wheels (number of days)	3.60 (21.00)	1.86 (21.97)	1.74 (-3.25 to 6.74)
Special equipment (number of items)	0.20 (0.75)	0.37 (1.03)	-0.17 (-0.38 to 0.04)
Patient and carer			
Home care (number of hours)	3.31 (6.99)	4.11 (8.57)	-0.80 (-2.63 to 1.02)
Time costs (number stopped working)	0.01 (0.16)	0.04 (0.28)	-0.02 (-0.08 to 0.03)

TABLE 3: Mean (Standard Deviation) cost and cost difference (95% Confidence Interval) per patient over the 12 months for first eye cataract surgery and no cataract surgery (in 2004 pounds sterling)

Resource use item	Surgery (n=148)	No surgery (n=140)	Mean difference (95% CI)
Secondary health care	£2312 (£2,033)	£881 (£1,175)	£1432 (£1,049 to £1,815)
Cataract Operation	£672 (£0)	£72 (£209)	£600 (£565 to £635)
Outpatients first and follow-up visit	£1,066 (£751)	£520 (£687)	£546 (£379 to £713)
Cost per bed day	£519 (£1,703)	£193 (£535)	£326 (£36 to £616)
A&E	£32 (£71)	£10 (£31)	£22 (£9 to £34)
Lower limb fractures	£5	£6	-£0

	(£64)	(£66)	(-£15 to £15)
Upper limb fractures	£17.39 (£121.31)	£79.66 (£306.95)	-£62 (-£117 to -£7)
Primary health care	£146 (£133)	£137 (£113)	£9 (-£19 to £38)
GP (number of visits)	£99 (£80)	£106 (£104)	-£7 (-£28 to £15)
Practice/district nurse	£47 (£90)	£31 (£32)	£16 (£1 to £32)
Personal social services	£791 (£3,113)	£231 (£593)	£560 (£45 to £1,075)
LA home care worker	£147 (£482)	£113 (£377)	£35 (-£65 to £135)
Day centre visits	£48 (£234)	£43 (£279)	£5 (-£55 to £65)
Residential care	£546 (£3,056)	£28 (£198)	£517 (£20 to £1,015)
Nursing home care	£0 (£0)	£10 (£91)	-£10 (-£26 to £5)
Meals on wheels	£28 (£164)	£14 (£171)	£14 (-£25 to £53)
Special equipment	£22 (£94)	£22.02 (£79)	-£0 (-£20 to £20)
Patient and carer	£453 (£1,069)	£620 (£1,640)	-£167 (-£490 to £157)
Home care	£396 (£847)	£471 (£969)	-£74 (-£286 to £137)
Time costs	£56 (£686)	£149 (£1,164)	-£93 (-£316 to £131)

Table 4: Summary of incremental cost utility ratios for first eye cataract surgery (in 2004 pounds sterling)

	ICER over 1 year	ICER over lifetime
Base case, public sector costs only	£35,704	£13,172
Base case, carer costs included	£32,391	£10,382
2% highest cost participants (n=3) excluded, public sector costs only	£27,205	£7,401
5% highest cost participants (n=7) excluded, public sector costs only	£18,386	£1,741
QoL improvement applies from time of operation, public sector costs only	£34,220	£13,097
QoL improvement gradual over 6 months, public sector costs only	£46,033	£13,445

Figure 1: Cost effectiveness acceptability curve (CEAC) for first eye cataract surgery versus no surgery in the base case over the one year trial period

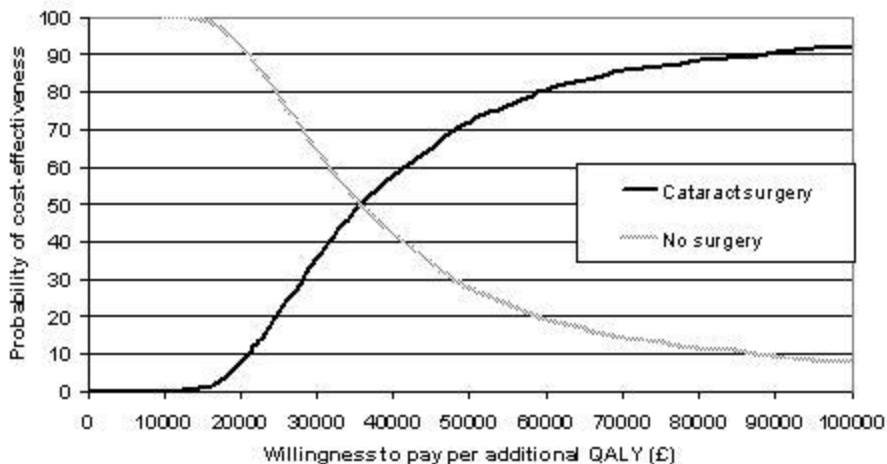


Figure 2: Cost effectiveness acceptability curve (CEAC) for first eye cataract surgery versus no surgery in the base case over participants remaining life expectancy (longer term model)

