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Day care versus in-patient surgery for age-related cataract (Review)

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[Intervention Review]

Day care versus in-patient surgery for age-related cataract

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ABSTRACT

Background

Age-related cataract accounts for more than 40% of cases of blindness in the world with the majority of people who are blind from cataract living in lower income countries. With the increased number of people with cataract, it is important to review the evidence on the effectiveness of day care cataract surgery.

Objectives

To provide authoritative, reliable evidence regarding the safety, feasibility, effectiveness and cost-effectiveness of day case cataract extraction by comparing clinical outcomes, cost-effectiveness, patient satisfaction or a combination of these in cataract operations performed in day care versus in-patient units.

Search methods

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (2015, Issue 7), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to August 2015), EMBASE (January 1980 to August 2015), Latin American and Caribbean Health Sciences Literature Database (LILACS) (January 1982 to August 2015), the ISRCTN registry (www.isrctn.com/editAdvancedSearch), ClinicalTrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 17 August 2015.

Selection criteria

We included randomised controlled trials comparing day care and in-patient surgery for age-related cataract. The primary outcome was the achievement of a satisfactory visual acuity six weeks after the operation.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data. We contacted study authors for additional information. We collected adverse effects information from the trials.

Main results

We included two trials. One study was conducted in the USA in 1981 (250 people randomised and completed trial) and one study conducted in Spain in 2001 (1034 randomised, 935 completed trial). Both trials used extracapsular cataract extraction techniques that are not commonly used in higher income countries now. Most of the data in this review came from the larger trial, which we judged to be at low risk of bias.



The mean change in visual acuity (in Snellen lines) of the operated eye four months postoperatively was similar in people given day care surgery (mean 4.1 lines standard deviation (SD) 2.3, 464 participants) compared to people treated as in-patients (mean 4.1 lines, SD 2.2, 471 participants) (P value = 0.74). No data were available from either study on intra-operative complications.

Wound leakage, intraocular pressure (IOP) and corneal oedema were reported in the first day postoperatively and at four months after surgery. There was an increased risk of high IOP in the day care group in the first day after surgery (risk ratio (RR) 3.33, 95% confidence intervals (CI) 1.21 to 9.16, 935 participants) but not at four months (RR 0.61, 95% CI 0.14 to 2.55, 935 participants). The findings for the other outcomes were inconclusive with wide CIs. There were two cases of endophthalmitis observed at four months in the day care group and none in the in-patient group. The smaller study stated that there were no infections or severe hyphaemas.

In a subset of participants evaluated for quality of life (VF14 questionnaire) similar change in quality of life before and four months after surgery was observed (mean change in VF14 score: day care group 25.2, SD 21.2, 150 participants; in-patient group: 23.5, SD 25.7, 155 participants; P value = 0.30). Subjective assessment of patient satisfaction in the smaller study suggested that participants preferred to recuperate at home, were more comfortable in their familiar surroundings and enjoyed the family support that they received at home. Costs were 20% more for the in-patient group and this was attributed to higher costs for overnight stay.

Authors' conclusions

This review provides evidence that there is cost saving with day care cataract surgery compared to in-patient cataract surgery. Although effects on visual acuity and quality of life appeared similar, the evidence with respect to postoperative complications was inconclusive because the effect estimates were imprecise. Given the wide-spread adoption of day care cataract surgery, future research in cataract clinical pathways should focus on evidence provided by high quality clinical databases (registers), which would enable clinicians and healthcare planners to agree clinical and social indications for in-patient care and so make better use of resources.

PLAIN LANGUAGE SUMMARY

Same day surgery compared to overnight stay for treatment of cataract caused by old age

Review question

Is day care surgery as effective, safe and feasible for treatment of cataract as in-patient surgery?

Background

The lens in the eyes can become cloudy with age (called cataracts), leading to blurry vision or total vision loss. Cataracts can be surgically removed by breaking up the lens and removing the pieces with a needle (a process called phacoemulsification), followed by the placing of an artificial lens to restore vision. This method of surgery is quick and together with a shorter recovery period has made the possibility of day surgery a reality. We wanted to find out whether operation in a day care unit was as effective and safe as staying overnight after an operation to replace the lens and regain better vision. Furthermore, we were interested to know what the side effects, risks and complications were of the two different approaches. We took into account improvement in quality of life and differences in costs.

Study characteristics

The review included two trials (up to August 2015) conducted in Spain and the USA, involving 1284 people with cataract. A total of 68 people were treated as day care surgery, while 598 stayed overnight in the hospital. The mean age of the participants was about 70 years and there were slightly more women than men. The studies were not funded by a drug company.

Key results

The two studies in this review found that in developed countries at least, there was some evidence that day surgery for this type of cataract extraction may not only be cheaper but just as effective as hospitalisation and overnight stay for cataract extraction. Although the evidence on complications after surgery such as swelling of the cornea, leaking of the wound and temporary increased pressure within the eye was inconclusive, there appeared to be little differences in visual acuity and improvements in quality of life.

Quality of evidence

One of the two studies showed limitations in study design and the way it was run, probably as it was an old study and reported in a less robust way. It provided fewer data for the review. The people included in the studies were representative for the group we were interested in.



BACKGROUND

Age-related cataract accounts for more than 40% of cases of blindness throughout the world with the majority of people blind from cataract found in the developing world (Limburg 2009; Riaz 2006). In 1999, the World Health Organization (WHO) and the International Agency for the Prevention of Blindness (IAPB) launched a joint initiative known as "VISION 2020: The Right to Sight," which aims to eliminate avoidable blindness by 2020 (WHO 1997). With the development of prevention of blindness programmes in many countries, an increasing number of people with cataracts are gaining access to surgical treatment for their ailment (Kupfer 1994). Nevertheless, the number of people blind as a result of cataract is increasing due to changes in the demographic structure of populations, the most important of which is increased life expectancy (Limburg 1996; Minassian 1990; Thylefors 1998). One study, Rapid Assessments of Avoidable Blindness (RAAB) (Limburg 1997), in Eritrea demonstrated an adjusted prevalence of bilateral blindness with available correction for people aged 50 years and older was 7.5% (95% confidence interval (CI) 6.2% to 8.8%) (Müller 2011). The prevalence of blindness in Eritrea is high if compared with reported blindness rates of about 2.0% for other African countries, China and most Latin American countries (Limburg 2009; Müller 2011; Xiao 2010). Surgery is the only effective treatment for cataract and, therefore, it is important to review the safety, effectiveness and ultimately the cost effectiveness of various modes of surgery.

Description of the condition

A cataract is opacity of the cortex or capsule of the lens (or both) and each type of cataract can have different characteristics. People can present with one or more of the following symptoms: gradual diminution of visual acuity, glare, decreased contrast sensitivity, frequent change in glasses prescription and change in colour appreciation (Rosenberg 2008). The condition is usually found by a primary care physician or optometrist, followed by referral to an ophthalmic surgeon for confirmation of the diagnosis and management. Access to eye tests varies by socioeconomic deprivation in England (Shickle 2015) and distance from optician (Simons 2009). Many people with treatable visual impairment from cataract do not access health services, mainly due to socioeconomic considerations (Desai 1999).

Description of the intervention

Surgical removal of the cataract is currently the only treatment option once the lens has opacified. This is usually accompanied by implantation of an artificial intraocular lens (IOL) to replace the natural lens.

How the intervention might work

Present day cataract surgery and IOL implantation allow accurate prediction of postoperative visual acuity. Several refinements have been made in surgical techniques in order to offer better postoperative clinical outcomes. The most notable revolution in cataract surgery in the last two decades was the change from the large 10-mm incision extracapsular cataract extraction procedure to the small 3- to 4-mm incision operation, which is known as phacoemulsification. Phacoemulsification involves fragmenting the lens inside the eye prior to its aspiration via a wide bore needle. This change is generally perceived to offer greater predictability of refractive outcomes, a shorter convalescence and faster recovery

of full visual function. A Cochrane systematic review comparing different surgical approaches for treatment of age-related cataract was published in *The Cochrane Library* (Riaz 2006).

Why it is important to do this review

With the advent of phacoemulsification in the early 1990s and the increasing use of local anaesthesia in cataract extraction, there has been a gradual trend towards management of people with cataracts as day cases. Such a trend was initially driven by the necessity of cost containment, the need to shorten waiting list times and to increase the capacity of health care providers in performing more surgeries per unit of time significantly. With increasing demand, 'stand alone' day care centres have opened both in the public and private sectors. These centres are able to offer diagnostic and treatment facilities for people with cataracts including day case cataract extraction operations that are usually performed under local anaesthesia (Cresswell 1996; Mojon-Azzi 2007). A more recent modification to the method of delivery of cataract surgery under local anaesthesia that is being used increasingly for highly selected cases is 'Cataract Surgery by Appointment'. The direct arrival of the person at the operating theatre, having self prepared for surgery, avoids admission to the ward or time spent in the day case unit and can result in a stay of as little as 20 minutes from arrival to discharge (Mavrikakis 2006).

Initial concerns about the quality of service provided by day care units and purpose-built centres delayed the wider spread of day care surgery. Most notable were concerns about whether this treatment modality has the same clinical outcome as the classic in-patient procedure and whether it carries a higher risk of intraoperative or postoperative complications (or both). An equally important aspect was the person's perspective of such an experience; that is would people prefer to undergo surgery done in such day care units or alternatively with full in-patient admission? However, one study by Tey et al., which examined different ways of streamlining cataract surgery services, found that a multifaceted approach that included increased utilisation of cataract nursing staff based in one-stop cataract clinics resulted in an increased number of day care surgery cases without any compromise in quality (Tey 2007).

Several non-controlled studies have compared the clinical outcome and cost-effectiveness of cataract extraction performed in day care units with those done as in-patients, (Ahmed 2011; Cillino 2007). This review provides an objective evaluation and comparison between two different concepts in healthcare planning and management. In addition, it serves as a stimulus for examining major changes in treatment modalities driven and supported by evidence-based patient choice.

OBJECTIVES

To provide authoritative, reliable evidence regarding the safety, feasibility, effectiveness and cost-effectiveness of day case cataract extraction by comparing clinical outcomes, cost-effectiveness, patient satisfaction or a combination of these in cataract operations performed in day care versus in-patient units.



METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials.

Types of participants

We considered trials in which participants were people with agerelated cataract. We placed no restrictions on race, gender or ocular co-morbidity.

Types of interventions

We included trials in which cataract extraction and IOL implantation done as day cases were compared to in-patient cases.

Types of outcome measures

Primary outcomes

 Achievement of a best-corrected visual acuity of 6/18 or better in the operated eye, six weeks after the operation.

Secondary outcomes

- · Adverse effects.
- Intraoperative complications including the proportion of participants with posterior capsular rupture with or without vitreous loss, misplaced IOLs and anaesthesia-related complications.
- Postoperative complications including the proportion of participants with wound leakage and other suture-related problems, corneal oedema or decompensation (or both), secondary glaucoma and postoperative endophthalmitis.
- Quality of life measures: participant-reported outcomes using any of the standard questionnaires to assess quality of life and visual function (e.g. VF14, 36-item Short Form (SF-36), etc.). We also considered subjective assessment of participant satisfaction of the procedure.
- Economic data: cost-effectiveness of the procedures carried out as day case and in-patient.

Search methods for identification of studies

Flectronic searches

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (2015, Issue 7), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to August 2015), EMBASE (January 1980 to August 2015), Latin American and Caribbean Health Sciences Literature Database (LILACS) (January 1982 to August 2015), the ISRCTN registry (www.isrctn.com/editAdvancedSearch), ClinicalTrials.gov (www.clinicaltrials.gov) and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 17 August 2015.

See: Appendices for details of search strategies for CENTRAL (Appendix 1), MEDLINE (Appendix 2), EMBASE (Appendix 3), LILACS

(Appendix 4), ISRCTN (Appendix 5), ClinicalTrials.gov (Appendix 6) and the ICTRP (Appendix 7).

Searching other resources

We searched the reference lists of relevant articles and the review authors' personal database of trial reports. We contacted investigators of included studies by electronic mail to ask for details of additional published and unpublished trials. We did not handsearch any journals or conference proceedings.

Data collection and analysis

Selection of studies

Two review authors independently assessed the abstracts of studies resulting from the searches. We obtained full copies of all relevant and potentially relevant studies, those appearing to meet the inclusion criteria, or for which there were insufficient data in the title and abstract to make a clear decision. These two review authors assessed the full-text papers independently and resolved any disagreement on the eligibility of included studies through discussion and consensus, or if necessary through a third party. After assessment, the review authors eliminated from further review any remaining studies that did not match the inclusion criteria and noted the reasons for their exclusion in the Characteristics of excluded studies table.

Data extraction and management

Two review authors independently collected study details and outcomes data using a predetermined form designed for this purpose. We entered study details into the Characteristics of included studies table in Review Manager 5 (RevMan 2014). The review authors only included data if there was an independently reached consensus, any disagreements were resolved by consulting with a third review author.

We extracted the following details.

Study methods

- Method of allocation.
- Masking of participants, investigators and outcomes assessment.
- Exclusion of participants after randomisation and proportion of losses at follow-up.

Participants

- · Country of origin.
- Sample size.
- Age.
- Sex.
- Inclusion and exclusion criteria.

Intervention

• Duration and length of time in follow-up.

Control

• Duration and length of time in follow-up.



Outcomes

 Primary and secondary outcomes mentioned in the Types of outcome measures section.

The review authors used this information to help them assess heterogeneity and the external validity of any included trials.

Assessment of risk of bias in included studies

Each review author then assessed the risk of bias of the selected studies independently using Cochrane's tool for assessing risk of bias as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). These review authors compared the assessments, and discussed and resolved any inconsistencies in their assessments.

We assessed the following domains as 'low risk of bias', 'unclear risk of bias' (uncertain risk of bias) or 'high risk of bias':

- random sequence generation;
- · allocation concealment;
- blinding (masking) of participants and personnel;
- masking of outcomes assessment;
- · incomplete outcome data;
- · selective outcome reporting;
- other bias.

The 'Risk of bias' section in the Characteristics of included studies table reports these assessments.

We also categorised and reported the overall risk of bias of each of the included studies according to the following:

- low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria were met;
- unclear risk of bias (plausible bias that raises some doubt about the results) if one or more criteria were assessed as unclear or
- high risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria were not met.

Assessment of heterogeneity

We included only two trials in this review and thus no assessment of heterogeneity was carried out. If we identify and include further trials in future updates, then we will use the following methods.

We will assess clinical heterogeneity by examining the characteristics of the studies, the similarity between the types of participants, the interventions and the outcomes as specified in the Criteria for considering studies for this review.

We will assess statistical homogeneity using a Chi^2 test and use the I^2 test to quantify inconsistency across any included studies. The I^2 test describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance) and where a value greater than 50% may be considered substantial heterogeneity (Higgins 2003).

Assessment of reporting biases

If we identify further trials for inclusion in this review, we will assess publication bias according to the recommendations on testing for funnel plot asymmetry as described in Chapter 10 of the *Cochrane*

Handbook for Systematic Reviews of Interventions (Sterne 2011), and explore these in the discussion if appropriate.

Data synthesis

We planned to present risk ratios for visual acuity outcomes and odds ratios for adverse effect outcomes. Since only one study provided adequate data, we did not perform a statistical summary.

Sensitivity analysis

We planned to conduct a sensitivity analysis to assess the robustness of our review results by repeating the analysis with the following adjustments: exclusion of studies of lower methodological quality and unpublished studies.

RESULTS

Description of studies

Results of the search

The initial electronic searches in November 2002 identified 226 references. After review, we excluded all but six papers from the review. We obtained full-text copies of these papers for further assessment. One paper described a systematic review (Castells 2000). We rejected one trial as the study compared day stay in a peripheral clinic with a main eye hospital and all participants were treated as day stay (Rose 1999). We rejected Ingram 1980 as no IOL implantation was carried out and the technique used (intracapsular cataract extraction) is now considered obsolete and the study cannot be relied on in comparison with the current technique of extracapsular cataract extraction. We were unsuccessful in obtaining additional data from the authors of Percival 1992 and were unable to assess its quality and thus excluded this trial. We discarded Lowe 1992 as the study only considered suitability for day case cataract surgery and did not include a comparison of inpatient or day care for cataract surgery. Two trials met the inclusion criteria for relevance and quality and were included in the review (Castells 2001; Galin 1981).

Updated searches

We updated the electronic searches in September 2004 and identified a further 85 references but found no new trials. In September 2006, we updated the searches again and identified 86 new reports of studies. After initial assessment by the Trials Search Co-ordinator for the Cochrane Eyes and Vision Group, we excluded 83 references, as they were not relevant to the scope of the review. We assessed the three remaining reports and obtained hard copies of two trials but neither were eligible for inclusion in the review.

An update search was done in September 2008. The electronic searches retrieved 171 titles and abstracts. After deduplication, the Trials Search Co-ordinator scanned 114 records and discarded 59 records as they were not relevant to the review. We screened the title and abstracts of the 55 remaining references but none met the inclusion criteria for the review.

We ran an updated search in May 2011. The electronic searches yielded 91 titles and abstracts. After deduplication, the Trials Search Co-ordinator scanned 83 records and discarded 70 records, as they were not relevant to the review. We screened the title and abstracts of the remaining 13 references but none were eligible for inclusion in the review.

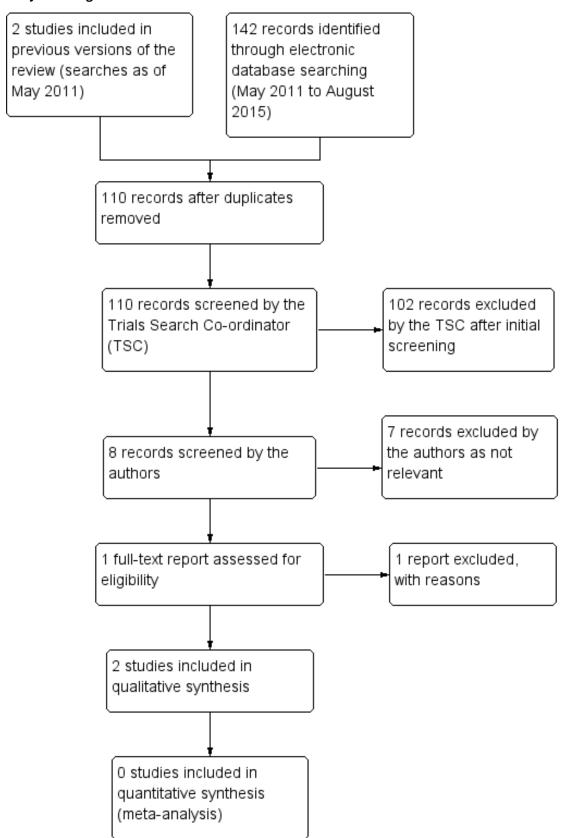


Further searches run in August 2015 identified 142 new records (Figure 1). The Trials Search Co-ordinator removed 32 duplicate records, screened the remaining 110 records and removed 102 references that were not relevant to the review. We screened the

remaining eight references and discarded seven reports, as they were not relevant. We obtained one full-text report (Cabric 2014), but excluded it, as it did not meet the inclusion criteria, see Characteristics of excluded studies table for details.



Figure 1. Study flow diagram.





Included studies

Summary of trial details

The Castells 2001 study was an unmasked randomised clinical trial of people undergoing cataract surgery in three public hospitals in Barcelona (Spain) in which 1034 participants were randomly assigned to one of two groups: out-patient hospital and in-patient hospital. People were eligible if they were scheduled for cataract surgery that did not include any other ophthalmological procedure and if they met certain inclusion criteria for ambulatory surgery. A total of 464 out-patients and 471 in-patients completed the trial. For the majority of participants, the planned procedure was extracapsular cataract extraction with IOL implantation. Of these participants, 17.5% out-patients and 16.6% in-patients underwent phacoemulsification.

The primary outcomes were postoperative complications within 24 hours of surgery, postoperative complications between 24 hours and four months after surgery, visual acuity of the operated and the better eye four months after surgery, and change in visual acuity pre- and postoperatively. Secondary outcomes focused on the evaluation of self reported outcomes that were administered by trained interviewers by telephone in the preoperative and fourmonth postoperative period. Visual function was assessed using the VF14 Index. The Cataract Symptom Score was used to measure the degree of difficulty caused by five symptoms common to people with cataracts. Additionally, the trial used the Sickness Impact Profile to assess participant's perceived health status and

sickness-related dysfunction. Economic data relating to direct costs associated with the surgery, in-patient stay and four-month follow-up were estimated and calculated per participant.

In the Galin 1981 study, 273 people who needed cataract surgery were asked to participate and 250 were randomised into three agematched groups. Cataract extraction was performed either with or without a Sputnik IOL. After completion of surgery, participants stayed in a hospital or a hotel or went home. Details regarding postoperative outcomes were very sparse. The study provided some detail on the cost of hotel stay but there was no information available on direct costs incurred as a result of the surgical procedure.

Further details of these trials can be found in the Characteristics of included studies table.

Excluded studies

See the Characteristics of excluded studies table.

Risk of bias in included studies

The Castells 2001 study met all but one of the criteria and was graded as 'unclear' risk of bias. Galin 1981 did not match several of the criteria completely and was also graded as 'unclear' risk of bias.

See Assessment of risk of bias in included studies and the summaries in Figure 2 and Figure 3.



Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

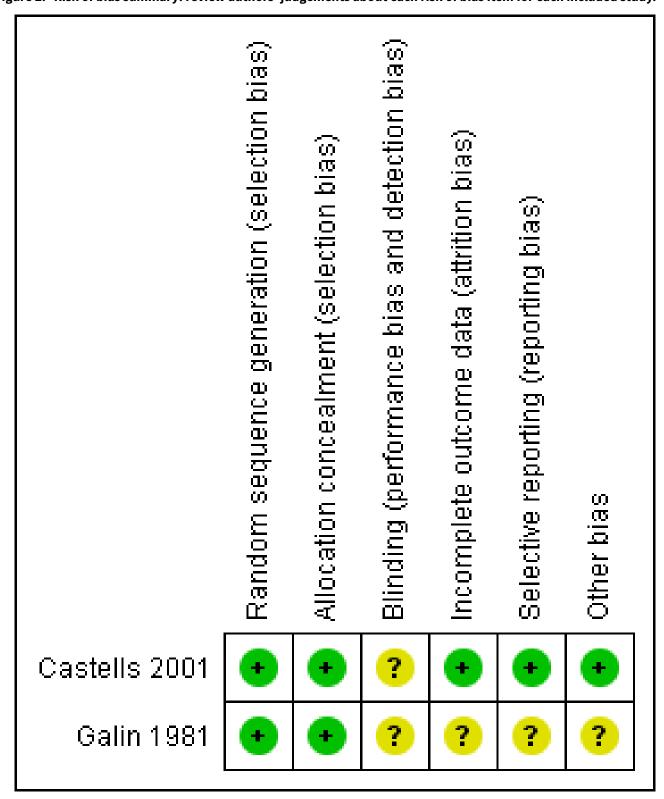
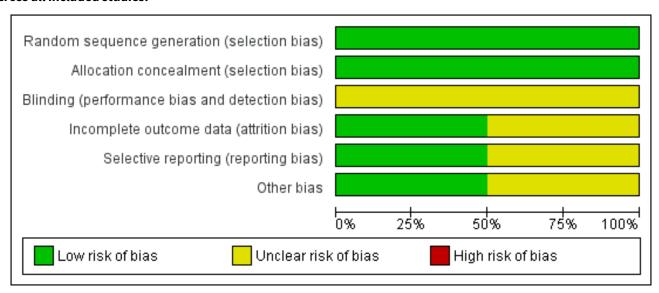




Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Allocation

The methods used to generate the allocation sequence and how the sequence was concealed, such that participants and investigators enrolling participants could not foresee the upcoming assignment, are the most important and sensitive indicators that bias has been minimised in a clinical trial (Schulz 1995). For both studies, we judged sequence generation and concealment of the allocation sequence as low risk of bias (see 'Risk of bias' tables in Characteristics of included studies table).

Blinding

One of the studies was unmasked but while the masking of participants and healthcare providers may not have been feasible, the masking of outcomes assessors was possible and of significant importance in this trial (Castells 2001). In the other study, the surgeon was unaware of the allocated assignment preoperatively but the report was unclear if the outcomes assessors, which may have included the investigators, knew which of the participants had been hospitalised or had been assigned to day care, at the follow-up assessment on the day after surgery (Galin 1981). We judged both studies as unclear risk of bias for this domain.

Incomplete outcome data

The data in Castells 2001 were adequately addressed in a flowchart. However, as the data in Galin 1981 were presented in a narrative style, it was not possible to confirm if all data had been satisfactorily reported.

Selective reporting

Although the protocols were not available for the two included studies, based on the information in the methods section of the reports, all pre-specified outcomes appear to have been reported and, therefore, we judged the studies free of selective reporting.

Other potential sources of bias

Castells 2001 appeared to be free of other bias, but there was insufficient information in Galin 1981 to assess whether there were any additional sources of bias.

Effects of interventions

The marked heterogeneity in the two included studies did not support undertaking any statistical analysis. We have presented a descriptive summary of results. All data are from Castells 2001 unless stated otherwise.

Primary outcomes

We had originally proposed to report on primary outcomes six weeks postoperatively but neither of the included studies reported outcomes for this time period. Thus, we reported on best-corrected visual acuity 6/18 or better in the operated eye four months postoperatively.

Visual acuity

The mean change in visual acuity (in Snellen lines) of the operated eye four months postoperatively was not statistically significant (4.1, standard deviation (SD) 2.3 with day care versus 4.1, SD 2.2 with in-patient; P value = 0.74) (Table 1).

Secondary outcomes

Intraoperative complications

No data were available from either study on intraoperative complications.

Postoperative complications

Castells 2001 reported statistically significant differences in early postoperative complication rates (Table 2) with an increased risk of increased IOP in the day care group that appeared to have no clinical relevance to visual outcomes four months postoperatively (Table 3). Although the four-month postoperative outcomes were similar between groups, there were nevertheless two participants



with endophthalmitis in the day care group versus none in the inpatient group. Galin 1981 stated that there were no infections or severe hyphaemas.

Quality of life measures

At four months postoperative, VF14 scores were higher for the day care group (92.8 with day care versus 87.6 with in-patient) and the mean change VF14 scores showed minimal differences between the two groups (25.2, SD 21.2 with day care versus 23.5, SD 25.7 with in-patient; P value = 0.30) (Table 4). Additional data provided were the Cataract Symptom Score to assess cataract-related symptoms and the Sickness Impact Profile Score, which assesses the overall perceived health status by measuring sickness-related dysfunction and confirmed that the perceived health outcomes were similar in both groups. The mean Cataract Symptom Score (range 0 to 15) four months after surgery was 0.6 (1.2) for the day care group and 0.8 (1.7) for the in-patient group. The Mean Sickness Impact Profile score (range 0 to 100) four months after surgery was 8.4 (8.9) for the day care group and 8.8 (8.8) for the in-patient group. Galin 1981 provided further subjective assessment of participant satisfaction who noted that participants preferred to recuperate at home, were more comfortable in their familiar surroundings and enjoyed the family support that they received at home.

Economic data

Direct costs including a four-month follow-up reported by Castells 2001 were 20% more for in-patient versus day care groups and attributed to higher costs for overnight stay (Table 5). Galin 1981 only reported hotel costs for the non-hospitalised participants making aggregation of data on costs impossible.

DISCUSSION

Summary of main results

The lack of high quality trials to synthesise was disappointing as the significance of this review in supporting a shift in methodology from in-patient to day care surgery can at present only be assessed by subjective means. However, it is readily apparent that this shift has already taken place, seemingly validated by experientially based opinion. The data that we reviewed produced no surprises and appears to provide confirmatory evidence of the safety, effectiveness and cost-effectiveness of day care cataract surgery. By way of further confirmation of the results, the Castells 2001 study showed similar mean changes in visual acuity between the two groups, which compared favourably with those found in the US National Study of Surgery Outcomes (Steinberg 1994). It was apparent from this study that the effectiveness of cataract surgery performed as a day case procedure, assessed by visual acuity, equals that of the corresponding in-patient procedure and thereby provides clinicians with a certain degree of confidence in the selection of a day care approach.

Overall completeness and applicability of evidence

Although there were statistically significant differences in immediate postoperative complications between the two groups, these did not appear to have a marked effect on the overall postoperative complications, which should further minimise any unease with day care cataract surgery. The more subjective quality of life measures and visual function results provided further corroborative evidence of the effectiveness of day care surgery as

a preferred modality. Additionally, in this era of soaring healthcare costs and cost containment there is a perception that day care surgery should provide a more cost-effective approach in the treatment of cataract surgery, a premise that the two included studies appear to confirm. However, care should be taken in examining the balance sheet as there are hidden community costs that need to be included in the day care surgery equation, costs that may in the end support the change solely as a cost-shifting economic exercise.

The electronic searches identified one systematic review published in Spanish, which included the trials that we assessed in our review (Castells 2000). We arranged to have the review translated into English. In the translated copy, the authors indicated that the quality assessment of their included studies followed the guidelines of the Evidence-Based Medicine Working Group and the CONSORT (CONsolidated Standards Of Reporting Trials) Statement, which they further added; evaluate primary criteria (randomisation of assigned treatment, attrition and intention-to-treat analyses) and secondary criteria (masking). We reviewed all the included studies and found ourselves unable to concur with all of the quality assessments made by the authors of some of these studies and additionally noted that this Spanish systematic review was not referenced in the Database of Abstracts of Reviews of Effects (DARE) in *The Cochrane Library*.

Quality of the evidence

Limitations in study design and implementation

Our assessments of risk of bias in Galin 1981 highlighted some of the limitations in the quality of this study, whereas the Castells 2001 study was more robust in design and reporting and allowed some conclusions to be drawn about the effectiveness, safety and cost-effectiveness of day care cataract surgery.

Indirectness of the evidence

The two trials compared in-patient care with day care and reported both clinician and participant preferred outcomes that provided evidence of direct relevance to clinical decision making.

Unexplained heterogeneity or inconsistency of results

Only two trials were included in this review and, although there was a degree of clinical diversity between the studies, it was not possible to pool any of their data and, therefore, we did not carry out an assessment of heterogeneity.

Imprecision of results

A lack of outcomes data from both trials did not enable any pooling or any assessment of the degree of precision of effect.

Publication bias

In view of the low number of trials included in this review, this assessment was not estimable.

Potential biases in the review process

Stringent attempts were made to limit bias in the review process by ensuring a comprehensive search for potentially eligible studies. The review authors' independent assessments of eligibility of studies for inclusion in this review and the extraction of data



minimised the potential for additional bias beyond that detailed in the 'Risk of bias' tables.

Agreements and disagreements with other studies or reviews

We are not aware of any other reviews that have covered this research question. There are no disagreements with earlier versions of this review.

AUTHORS' CONCLUSIONS

Implications for practice

This review based on two trials conducted in the developed world provides some evidence that there is a cost saving but no significant difference in outcome or risk of postoperative complications between day care and in-patient cataract surgery. Evidence regarding people's preferences for day case cataract surgery versus in-patient admission was inconclusive.

However, these randomised controlled trials (RCTs) were conducted some time ago and it is unlikely that new RCTs will be attempted. Therefore, the resolution of some of the questions about the safety and cost-effectiveness of cataract surgery in day care centres should be elucidated using data from high quality clinical databases or registries, such as the Cataract Surgery Registry set up in Malaysia (Cataract Surgery Registry Malaysia 2002). This should enable clinicians and healthcare planners to agree clinical and social indications for in-patient care and so make better use of resources, by selecting day case surgery unless these criteria are met.

In the developed world, the resolution of some of the questions about the safety and cost-effectiveness of cataract surgery in day care centres should enable healthcare planners to make better use of resources, by selecting day case surgery unless there are agreed clinical and social indications for in-patient care. This could result in the freeing up of hospital beds and staff that would normally be required for in-patient cataract surgery. Although the review specifically considered economic data related to cost-effectiveness, some reference should be made to the possibility of any total cost saving in the change from day care to in-patient cataract surgery. There is some unease with the cost-saving premise in that the move to day case cataract surgery may be seen solely as a cost-shifting exercise, shifting the cost burden on to the community while removing it from the health service with possibly no total cost saving.

In the developing world with its funding and resource difficulties, consideration of the results of this review may encourage health policy planners to evaluate a possible wider adoption of 'cataract camps'. Although these programmes have been available since the early 1990s, there have been reservations expressed about the quality of care and possible postoperative complications. There are tangible benefits with improved access to care for medically underserved regions if fully equipped mobile units can visit out-reach

clinics and provide quality day care cataract surgery equivalent to that of in-patient care.

Implications for research

The sparse number of RCTs on this topic indicate that the progression from in-patient to day care as the primary treatment modality has already taken place in a shift driven by necessity, cost and a simplification of the procedure.

In the developed world, there does not appear to be any further debate about the safety and outcomes of day care cataract surgery, but there is controversy on appropriate thresholds for cataract surgery and the validity of participant-reported outcome measures (Black 2009).

Future research on these topics is required and should also explore issues of severity thresholds for when in-patient cataract surgery is appropriate. In the absence of additional RCTs, essential evidence could be provided by researchers working with clinicians to develop and use the high quality clinical databases noted above.

Future research in the developing world could well continue to focus on safety, outcomes, type of surgical procedure, as well as costs, all of which may help confirm the universal applicability of the findings from the developed world. It is important that additional trials pay greater attention to detail in their design and reporting and consider using the CONSORT (CONsolidated Standards Of Reporting Trials) Statement to ensure that important factors such as random allocation sequence, masked assessment and dealing with withdrawals are included.

Finally, we note that the design of the Castells 2001 study provides a sound template for measuring the benefits of surgery. It includes the use of participant assessed visual function via visual quality of life measures and moves away from a sole reliance on visual acuity with its widely acknowledged ability to capture only a limited aspect of visual function. More research on the validity and reliability of these participant-reported outcome measures is required so that consideration should also be given to a greater role for these participant-reported visual function and visual quality of life outcome instruments and specifically in the measurement of need for, and benefits from, surgery.

ACKNOWLEDGEMENTS

The Cochrane Eyes and Vision Group developed and executed the electronic searches for this review. We would like to acknowledge Anupa Shah, Iris Gordon, Henry Ejere and Katherine Henshaw for their guidance throughout this review. The review authors appreciate the contribution of Wael Wagih Hamed in first registering the title for this review and the help he provided with the development of the protocol. We thank Suad Al-Khalifa, Head Librarian at the Arabian Gulf University for her ongoing help. We thank Peter Gutierrez for his contribution to previous versions of this review.



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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

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Castells 2001



Castells 2001 (Continued)	Allocation 1 month pri	or to surgery, concealment by central allocation	
Participants	People with cataract from 3 public hospitals in Barcelona (Spain) n = 1162. After randomisation, n = 1034 (out-patients: n = 518, in-patients: n = 516) Withdrawals: 99. Completed trial: out-patients 464 (89.6%), in-patients 471 (91.3%) Mean age (SD): day care 71.6 years (10.7), in-patients 71.4 years (9.7) Gender (female): day care: 270 (58.2%), in-patients: 278 (59%)		
Interventions		extraction with intraocular lens implantation performed as day-care and extraction with intraocular lens implantation performed in hospital	
Outcomes	Late postoperative sur	complications (24-hour postoperative) gical complications (between 24 hours and 4 months) erated and better eye 4 months postoperative, change in visual acuity pre-post-	
Notes	Only 17.5% of the day	care and 16% of the in-patients underwent phacoemulsification	
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Low risk	Quote: "The randomisation was generated by computerised simple random number software"	
		Comment: done	
Allocation concealment	Low risk	Quote: "performed centrally by our research unit"	
(selection bias)		Comment: done	
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Quote: "An unmasked randomised clinical trial"	
		Participants: not feasible	
		Healthcare providers: not feasible	
		Outcomes assessors and data analysts:	
		Quote: "the outpatient hospital groupwere discharged home the same day after a visit by an ophthalmologist. They had an outpatient visit with an ophthalmologist 24h after surgery"	
		"In the inpatient hospital group, patients were admitted to an acute care hospital for at least one night after surgery and received hospital visit(s) by an ophthalmologist before hospital discharge"	
		Comment: while the masking of participants and healthcare providers may not have been feasible, the masking of outcomes assessors was possible and of significant importance in this trial. The trial report was unclear what steps were taken to limit the effects of performance bias	
Incomplete outcome data	Low risk	The report included a "trial randomisation flowchart"	
(attrition bias) All outcomes		Quote: "The results of the study have been analysed according to the intention to treat"	
		Comment: done	
Selective reporting (reporting bias)	Low risk	All of the study's pre-specified outcomes were reported	



Castells 2001 (Continued)

Other bias Low risk The study appeared to be free of other sources of bias

Galin 1981

Methods	Prospective randomised controlled trial	
Participants	Country of origin: USA n = 273, 23 refused. n = 250 age-matched (aged 50-79 years) people with cataracts, in-patients: n = 82, day care: n = 168 No attritional losses over 2-year follow-up period	
Interventions	Cataract extraction with or without a Sputnik intraocular lens	
	Randomised to hospital or hotel or immediate discharge to home	
Outcomes	Duration and cost per day of stay in hospital or hotel reported	
Notes	Data sparse largely narrative style	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence genera-	Low risk	Quote: "Using tables of coded random numbers"
tion (selection bias)		Comment: done
Allocation concealment (selection bias)	Low risk	Quote: "The surgeon did not know preoperatively in which category a patient belonged." "On the day of surgery, the patient reported to the registration office at the hospital, where a hospital chart number was assigned". "At the end of the procedure, the eye was patched and we opened a sealed envelope that indicated the patient's postoperative location"
		Comment: done
Blinding (performance	Unclear risk	Participants: not feasible
bias and detection bias) All outcomes		<u>Healthcare providers:</u> "The surgeon did not know preoperatively in which category a patient belonged"
		Outcomes assessors and data analysts: it was unclear if the outcomes assessors, which may have included the surgeons, knew which of the participants had been hospitalised or had been assigned to day care, at the follow-up assessment on the day after surgery
		Comment: masking of assessors was 'unclear'
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data sparse largely narrative style
Selective reporting (reporting bias)		
		Comment: 'ocular results' and postoperative complications were not specified. The report did not include the results for these key outcomes that would be expected to have been reported



Galin 1981 (Continued)

Other bias Unclear risk Insufficient information to assess whether an important risk of bias existed

n: number of participants; SD: standard deviation.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion	
Cabric 2014	The study randomised people to a day care cataract surgery (DCCS) group and an out-patient and in-patient surgery group. The paper reported that, "All patients in DCCS group were discharged day after cataract extraction." We have excluded this study as participants were not treated as day care attendees	
Ingram 1980	No intraocular lens implantation was carried out and study used the intracapsular cataract extraction technique, which is considered obsolete. Thus, the study cannot be relied on in a comparison with the current technique of extracapsular cataract extraction	
Lowe 1992	This study only considered suitability for day case cataract surgery and did not include a comparison of in-patient versus day case cataract surgery	
Percival 1992	Unable to assess trial quality and unable to obtain further information from authors	
Rose 1999	The study compared day stay participants in a peripheral clinic and a main eye hospital. All participants were treated as day stay	

ADDITIONAL TABLES

Table 1. Visual acuity four months postoperative (operated eye)

Visual acuity	Number of participants (%)	Number of participants (%)		
	Day care (total n = 464)	In-patient (total n = 471)		
< 6/18*	92 (19.8%)*	84 (17.8%)*		
> 6/18 to 6/15	111 (24%)	128 (27.2%)		
6/12 to 6/9	149 (32.1%)	161 (34.2%)		
6/9	112 (24.1%)	98 (20.8%)		
Mean change (SD)	4.1 (2.3)	4.1 (2.2)		

^{*}not primary outcomes.

n: number of participants; SD: standard deviation.

Table 2. Early (less than 24 hours) postoperative complications

Complications	Number of participants (%)		Risk ratio (95% CI)
	Day care (total n = 464)	In-patient (total n = 471)	_



Table 2.	Early	(less than 24 hours)	postoperative c	omplications (Continued)
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Wound leakage	5 (1.1%)	4 (0.8%)	1.27 (0.34 to 4.77)
Corneal oedema	49 (10.6%)	36 (7.6%)	1.42 (0.91 to 2.24)
Intraocular pressure > 30 mm Hg	16 (3.4%)	5 (1.1%)	3.33 (1.21 to 9.16)

CI: confidence interval; n: number of participants.

Table 3. Late (less than four months) postoperative complications

Complications	Number of participants (%)		Risk ratio (95% CI)
	Day care (total n = 464)	In-patient (total n = 471)	_
Corneal oedema	32 (6.9%)	24 (5.1%)	1.38 (0.80 to 2.38)
Wound leakage	4 (0.9%)	7 (1.5%)	0.76 (0.17 to 1.98)
Intraocular pressure > 30 mm Hg	3 (0.6%)	5 (1.1%)	0.61 (0.14 to 2.55)
Endophthalmitis	2 (0.4%)	0 (0.0%)	-

CI: confidence interval; n: number of participants.

Table 4. VF14 scores four months postoperative

VF14 scores	Day care (n = 150)	In-patient (n = 155)
Mean (SD) (range 0-100)	92.8 (12.2)	87.6 (20.3)
Change score pre-postoperative	25.2 (21.2)	23.5 (25.7)

n: number of participants; SD: standard deviation.

Table 5. Costs of cataract surgery

Costs	Day care (n = 150)	In-patient (n = 155)
Total costs in Euros (SD)	1001.3 (251.4)	1218.0 (187.3)

n: number of participants; SD: standard deviation.

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor Ambulatory Surgical Procedures

#2 MeSH descriptor Ambulatory Care

#3 MeSH descriptor Outpatient Clinics, Hospital

#4 day*

#5 car* OR case* OR surg*



#6 (#4 AND #5)

#7 (outpatient* or out-patient* (out next patient*))

#8 (#1 OR #2 OR #3 OR #6 OR #7)

#9 MeSH descriptor Hospitalization

#10 (inpatient* or in-patient*)

#11 hospital*

#12 (overnight* or over-night or (over next night*))

#13 (#9 OR #10 OR #11 OR #12)

#14 (#8 AND #13)

#15 MeSH descriptor Cataract

#16 cataract*

#17 (#15 OR #16)

#18 (#14 AND #17)

Appendix 2. MEDLINE (Ovid) search strategy

1 randomized controlled trial.pt.

2 (randomized or randomised).ab,ti.

3 placebo.ab,ti.

4 dt.fs.

5 randomly.ab,ti.

6 trial.ab,ti.

7 groups.ab,ti.)

8 or/1-7

9 exp animals/

10 exp humans/

11 9 not (9 and 10)

12 8 not 11

13 exp ambulatory surgical procedures/

14 exp ambulatory care/

15 exp outpatient clinics hospital/

16 (day adj3 (care or case\$ or surger\$)).tw.

17 outpatient\$.tw.

18 or/13-17

19 exp hospitalization/

20 (in?patient\$ or hospital\$ or over?night or over night).tw.

21 or/19-20

22 exp cataract extraction/

23 cataract\$.tw.

24 or/22-23

25 18 and 21 and 24

26 12 and 25

The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville (Glanville 2006).

Appendix 3. EMBASE (Ovid) search strategy

1 exp randomized controlled trial/

2 exp randomization/

3 exp double blind procedure/

4 exp single blind procedure/

5 random\$.tw.

6 or/1-5

7 (animal or animal experiment).sh.

8 human.sh.

97 and 8

10 7 not 9

11 6 not 10

12 exp clinical trial/

13 (clin\$ adj3 trial\$).tw.

14 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$)).tw.

15 exp placebo/

16 placebo\$.tw.



17 random\$.tw.

18 exp experimental design/

19 exp crossover procedure/

20 exp control group/

21 exp latin square design/

22 or/12-21

23 22 not 10

24 23 not 11

25 exp comparative study/

26 exp evaluation/

27 exp prospective study/

28 (control\$ or prospectiv\$ or volunteer\$).tw.

29 or/25-28

30 29 not 10

31 30 not (11 or 23)

32 11 or 24 or 31

33 exp ambulatory surgery/

34 exp outpatient care/

35 (day adj3 (care or case\$ or surger\$)).tw.

36 outpatient\$.tw.

37 or/33-36

38 exp hospitalization/

39 (in?patient\$ or hospital\$ or over?night or over night).tw.

40 or/38-39

41 exp cataract/

42 cataract\$.tw.

43 or/41-42

44 37 and 40 and 43

45 32 and 44

Appendix 4. LILACS search strategy

cataract\$ and day and hospital\$

Appendix 5. ISRCTN search strategy

cataract and day

Appendix 6. ClinicalTrials.gov search strategy

Cataract AND Day AND Hospital

Appendix 7. ICTRP search strategy

cataract AND day AND hospital

WHAT'S NEW

Date	Event	Description
18 August 2015	New search has been performed	Issue 11, 2015: An updated search in August 2015 yielded no new randomised controlled trials for inclusion.
18 August 2015	New citation required but conclusions have not changed	Issue 11, 2015: A number of new references have been added to the 'Background' and 'Discussion' sections. Some of the sections have been reorganised using new subheadings and the abstract and plain language summary have been edited to meet new Cochrane methodological standards.



HISTORY

Protocol first published: Issue 2, 2003 Review first published: Issue 1, 2004

Date	Event	Description
28 May 2011	New citation required but conclusions have not changed	A new co-author has joined the existing review team.
28 May 2011	New search has been performed	Issue 7 2011: An updated search in May 2011 yielded no new trials. A number of new references have been added to the 'Background' and 'Discussion' sections. Some of the sections have been reorganised using new subheadings.
20 October 2008	New search has been performed	Issue 1 2009: An updated search in September 2008 yielded no new trials. One additional reference (Tey 2007) has been added to the background section.
21 August 2008	Amended	Converted to new review format.
23 October 2004	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Conceiving the review: Wael Wagih Hamed, ZF.

Designing the review: ZF.
Co-ordinating the review: ZF.
Data collection for the review: ZF.
Screening search results: ZF, PG, EVZ.

Screening retrieved papers against inclusion criteria: ZF, PG, EVZ.

Appraising quality of papers: ZF, DL. Extracting data from papers: ZF, PG.

Writing to authors of papers for additional information: ZF.

Providing additional data about papers: ZF.

Obtaining and screening data on unpublished studies: ZF.

Data management for the review: ZF.

Entering data into Review Manager 5: ZF, PG.

Analysis of data: ZF.

Writing the review: ZF, DL, PG, EVZ.

Performing previous work that was the foundation of current study: ZF.

The 2015 version was jointly updated by DL, ZF and EVZ.

DECLARATIONS OF INTEREST

None known.

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 - o The NIHR also funds the CEVG Editorial Base in London.

The views expressed in this publication are those of the authors and not necessarily those of the NIHR, NHS, or the Department of Health.

INDEX TERMS

Medical Subject Headings (MeSH)

*Ambulatory Surgical Procedures [economics] [methods]; *Cataract Extraction [economics] [methods]; *Hospitalization [economics]; Feasibility Studies; Postoperative Complications; Quality of Life; Randomized Controlled Trials as Topic; Visual Acuity

MeSH check words

Humans