

Special Review

A Cochrane Systematic Review finds no significant difference in outcome or risk of postoperative complications between day care and in-patient cataract surgery

Zbigniew Fedorowicz, MScDPH, BDS, David J. Lawrence, MA, MPhil, Peter Gutierrez, MA.

ABSTRACT

This review was conducted to determine reliable evidence regarding the safety, feasibility, effectiveness, and cost-effectiveness of cataract extraction performed as a day care versus in-patient procedure. The search to identify randomized controlled trials comparing day care and in-patient surgery for age-related cataract included the Cochrane Eyes and Vision Group Trials Register, the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE and LILACS (Latin American and Caribbean Literature on Health Sciences). Assessment of methodological quality was based on criteria defined by the Cochrane Collaboration. The primary outcome was the achievement of a satisfactory visual acuity 6 weeks after operation. Two trials, involving a total of 1284 people, are included. One trial reported statistically significant differences in early postoperative complication rates in the day care group, which had no clinical relevance to visual outcomes 4 months postoperatively. Mean change in visual acuity (Snellen lines) of the operated eye 4 months postoperatively was 4.1 (standard deviation (SD) 2.3) for the day care group and 4.1 (SD 2.2) for the in-patient group. Costs were 20% more for the in-patient group attributable to higher costs for overnight stay.

Saudi Med J 2006; Vol. 27 (9): 1296-1301

From the UK Cochrane Centre, (Fedorowicz), Bahrain Branch, The Cochrane Collaboration, Public Health Directorate (Lawrence), Brent Primary Care Trust, Wembley, United Kingdom, Pfizer Health Solutions (Gutierrez), Santa Monica, California, United States of America.

Address correspondence and reprint request to: Dr. Zbigniew Fedorowicz, PO Box 25438, Awali, Bahrain. E-mail: zbyfedo@batelco.com.bh

This paper provides the essence of a Cochrane Review published in the Cochrane Electronic Library in January 2005 (see http://www3.interscience.wiley.com/aboutus/sharedfiles/cochrane_transition/ for further information). Cochrane Reviews are updated regularly in response to comments and criticism and as new evidence emerges. The Cochrane Library should be consulted for the most recent version of this Systematic Review.

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.¹ With the development of prevention of blindness programs in many countries, an increasing number of cataract patients are gaining access to surgical treatment for their ailment.² 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.³⁻⁵

Treatment options. Surgical removal of the cataract is currently the only treatment option once the lens has opacified. This is usually accompanied by implantation of an intraocular lens (IOL) to replace the focusing power of the natural lens. Modern 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 2 decades was the change from a 10 mm incision extracapsular cataract extraction procedure to the smaller 3-4 mm incision operation known as phacoemulsification. Phacoemulsification involves fragmenting the cataractous 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 Review¹ comparing different surgical approaches for treatment of age-related cataract is published in The Cochrane Library.

With the advent of phacoemulsification in the early 1990s and the increasing use of local anesthesia in cataract extraction, a trend has developed towards management of cataract patients as day cases. Such a trend was initially driven by the necessity

of cost containment, the need to shorten waiting list times and to significantly increase the capacity of health care providers in performing more surgeries per unit of time. With increasing demand, 'stand alone' day care centers arose both in the national and private sectors. Classically these centers offer diagnostic and treatment facilities for cataract patients including day case cataract extraction operations usually performed under local anesthesia.⁶ Concerns about the quality of service provided by day care units and purpose-built centers delayed the wider spread of day care surgery. Most notable concerns were whether this treatment modality has the same clinical outcome as the classic in-patient procedure and whether it carries a higher risk of intra and/or postoperative complications. An equally important aspect was the patient's perspective of such an experience, namely, would patients prefer to undergo surgery carried out in day care units or alternatively with full in-patient admission.

The objective of this review was to provide reliable evidence regarding the safety, feasibility, effectiveness and cost-effectiveness of day case cataract extraction by comparing clinical outcomes, cost-effectiveness and/or patient satisfaction in cataract operations performed in day care versus in-patient units.

Methods. *Types of studies.* Only randomized controlled clinical trials (RCTs) were considered in this review.

Types of participants. Only studies that had recruited participants with age related cataract. No restrictions were made on race, gender or ocular co-morbidity.

Types of interventions. We included trials in which cataract extraction and IOL implantation carried out as day cases were compared to in-patient cases.

Types of outcome measures. Primary. The achievement of a satisfactory visual acuity 6 weeks after the operation. Satisfactory visual acuity is defined here as best corrected visual acuity of 6/18 or better in the operated eye.

Secondary. 1. Adverse effects. 2. Intraoperative complications including the proportion of participants with posterior capsular rupture with or without vitreous loss, misplaced intraocular lenses and anesthesia related complications. 3. Postoperative complications including the proportion of participants with wound leakage and other suture related problems, corneal edema, and/or decompensation, secondary glaucoma, and postoperative endophthalmitis. 4. Patient reported outcomes using any of the validated tools to assess quality of life and visual function, for example, VF 14, SF 36. 5. Cost-effectiveness of the procedures carried out as day case and in-patient.

Search strategy for identification of studies. Electronic searches. Search strategies were developed for each database, to identify studies that could be included

or considered for this review. These strategies were based on the search strategy developed for MEDLINE, but were revised appropriately for each database. Trials were identified from the Cochrane Central Register of Controlled Trials - CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) on The Cochrane Library, MEDLINE, EMBASE and LILACS (Latin American and Caribbean Literature on Health Sciences). There was no language or date restrictions in the electronic searches. The detailed search strategy developed for each database is available in Issue 2, April 2006 of The Cochrane Library (http://www3.interscience.wiley.com/aboutus/sharedfiles/cochrane_transition/)

Handsearching. The authors did not conduct any handsearching, but examined the reference lists of the included clinical trials and the review authors' personal databases of trial reports to identify any additional studies as well as those not identified in the initial searches.

Review methods. Assessment of search results. Two review authors independently assessed the abstracts of studies that resulted from the searches. Full text copies of any relevant and potentially relevant studies were obtained, as were those that appeared to meet the inclusion criteria, and those whose title and abstract did not offer information sufficient for making a clear decision. The 2 review authors assessed full text papers independently, and any disagreement regarding the eligibility of included studies was resolved through discussion and consensus. All irrelevant records were excluded, and details of the studies and the reasons for their exclusion were noted.

Assessment of methodological quality. Each selected study was independently assessed by 2 reviewers using a simple contingency form, which used the criterion grading listed below. Discrepancies were settled by discussion and mutual agreement. We assessed 3 parameters of methodological quality: 1. Selection bias - whether the way in which individuals are accepted into a group or the way that interventions are assigned may affect the outcomes. 2. Detection bias - whether persons assessing the outcome of care were aware of which treatment the participant received. 3. Attrition bias - whether there was a substantial difference between the 2 groups regarding loss of participants from the study over the follow up period. Each criterion was graded A if the criterion was met, B if it was unclear, or C if the criterion had not been met. We attempted to obtain any missing information from investigators.

Data collection. Study details from RCTs meeting the inclusion criteria were entered into Review Manager (RevMan 4.2.2) by each reviewer separately and cross checked. The following details were extracted. 1. Study

methods: method of allocation, masking of participants and outcomes, exclusion of participants after randomization and proportion of follow up losses. 2. Participants: country of origin, sample size, age, gender, inclusion, and exclusion criteria. 3. Intervention: type of operation performed and average duration of hospital stay. 4. Outcomes: primary and secondary outcomes mentioned in the section of outcome measures. This information was used to help us assess heterogeneity and the external validity of the trials. Outcome data were collected using a form designed for this purpose. Extracted data were entered into RevMan 4.2.2 by each reviewer sequentially and automatically checked for differences.

Data synthesis. Pooling of data was not possible because of the diversity and heterogeneity in the included studies and therefore only a narrative synthesis of the data from these trials is presented.

Sensitivity analysis. Sensitivity analyses were not conducted for similar reasons.

Results. Finding the trials. The initial electronic searches identified 226 references. After review, all but 6 papers were excluded from the review. Full text copies of these papers were obtained for further assessment. One paper described a systematic review by Castells.⁷ One, a trial by Rose,⁸ was rejected as the study compared day stay in a peripheral clinic with a main eye hospital and all participants were treated as day stay. Ingram⁹ was rejected as no IOL implantation was carried out and the technique used intracapsular cataract extraction, which 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,¹⁰ and were unable to make an assessment of its quality and thus this trial was excluded. Lowe¹¹ was discarded as the study considered only suitability for day case cataract surgery and did not include a comparison of in-patient or day care for cataract surgery. Two trials Castells 2001; Galin 1981 (See References to included studies) met the inclusion criteria and are included in the review. The updated electronic searches identified a further 85 references but no new trials were found.

Summary of trial details. The Castells 2001 study was an unmasked RCT of patients undergoing cataract surgery in 3 public hospitals in Barcelona (Spain) in which 1034 participants were randomly assigned to one of 2 groups: out-patient hospital and inpatient hospital. Patients 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% inpatients underwent phacoemulsification. The primary outcomes were postoperative complications within 24 hours of surgery; postoperative complications between 24 hours and 4 months after surgery; visual acuity of the operated and the better eye 4 months after surgery; change in visual acuity pre and postoperatively. Secondary outcomes focused on the evaluation of self-reported outcomes, which were administered by trained interviewers by telephone in the preoperative and 4 month postoperative period. Visual function was assessed using the VF 14 Index. The Cataract Symptom Score was used to measure the degree of difficulty caused by 5 symptoms common to cataractous patients. Additionally, the Sickness Impact Profile was used to assess participants perceived health status and sickness related dysfunction. Economic data relating to direct costs associated with the surgery, in-patient stay and 4-month follow up were estimated and calculated per participant.

In the Galin 1981 study, 273 patients who needed cataract surgery were asked to participate and 250 were randomized into 3 age matched 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.

Methodological quality of included studies. The 2 included studies were of moderate quality. In Castells 2001, the participants were randomized by computerized simple random number software performed centrally by the research unit. Thus, the authors are deemed to have taken adequate measures to conceal allocation. Their report provided a trial randomization flowchart, which included study dropouts and those who did not undergo surgery, died or refused to be interviewed and those who did not receive the intervention to which they were allocated. Patients lost to follow up (attrition analysis) were accounted for and there were no differences in attrition in both groups either in the distribution of reasons for withdrawal or in their clinical characteristics. This study did not specifically mention any masking of outcomes assessment. Galin 1981, randomized participants using tables of coded random numbers. Allocation concealment was considered adequate. Only the number of people that refused or changed their minds were included in the report. The remaining data were sparse and included generalizations about the postoperative period, and the 2 year follow

up. A descriptive summary of results is presented. All data are from Castells 2001 unless stated otherwise.

Primary outcomes. We had originally proposed to report on primary outcomes 6 weeks postoperatively, but neither of the included studies reported outcomes for this time period. Thus, we report on best corrected visual acuity 6/18 or better in the operated eye 4 months postoperatively.

Visual acuity. The mean of change in visual acuity (in Snellen lines) of the operated eye 4 months postoperatively was 4.1 (standard deviation (SD) 2.3) day care and 4.1 (SD 2.2) in-patient and not statistically significant ($p = 0.74$) (Table 1).

Secondary outcomes. No data were available from either study on intraoperative complications. Castells 2001 reported statistically significant differences in early postoperative complication rates with an increased risk of increased intraocular pressure in the day care group, but which appeared to have no clinical relevance to visual outcomes 4 months postoperatively (Table 2). Although the 4-month postoperative outcomes were similar between both groups, there were nevertheless 2 patients with endophthalmitis in the day care group versus none in the in-patient group (Table 3). Galin 1981 merely stated that there were no infections or severe hyphemas.

Four months postoperatively VF 14 scores were higher for the day care group (92.8 versus 87.6) and the mean of change VF 14 scores showed minimal differences between the 2 groups, day care 25.2 (standard deviation (SD) 21.2) and inpatient 23.5 (SD 25.7) $p = 0.30$ (Table 4). Additional data provided were the Cataract Symptom Score and the Sickness Impact Profile Score, which assesses the overall perceived health status by measuring sickness related dysfunction, which confirmed that the perceived health outcomes were similar in both groups. The mean Cataract Symptom Score (range = 0-15) 4 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 = 0-100) 4 months after surgery was 8.4 (8.9) for the day care group and 8.8 (8.8) for the in-patient group. Further subjective assessment of patient satisfaction was provided by Galin 1981, 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 from the Castells 2001 trial revealed that direct costs, including a 4-month follow up, were 20% more for in-patient versus day care and attributable to higher costs for overnight stay (Table 5). Galin 1981 reported only hotel costs for the non-hospitalized participants making it impossible to aggregate economic data from both trials.

Table 1 - Visual acuity 4 months postoperative (operated eye).

Visual Acuity	Day-care (n = 464) n (%)	In-patient (n = 471) n (%)
<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 (24.2)	98 (20.8)
Mean change (SD)	4.1 (2.3)	4.1 (2.2)
*not primary outcomes		

Table 2 - Early (<24 hour) postoperative complications.

Complications	Day-care (n = 464) n (%)	In-patient (n = 471) n (%)	Relative Risk (CI)
Wound leakage	5 (1.1)	4 (0.8)	1.27 (0.34 to 4.77)
Corneal edema	49 (10.6)	36 (7.6)	1.42 (0.91 to 2.24)
Intraocular pressure >30mmHg	16 (3.4)	5 (1.1)	3.33 (1.21 to 9.16)

Table 3 - Late (<4 months) postoperative complications.

Complications	Day-care (n = 464) n (%)	In-patient (n = 471) n (%)	Relative Risk (CI)
Corneal edema	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 >30mmHg	3 (0.6)	5 (1.1)	0.61 (0.14 to 2.55)
Endophthalmitis	2 (0.4)	0 (0.0)	--

Table 4 - VF 14 scores 4 months postoperative.

VF 14 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-postop	25.2 (21.2)	23.5 (25.7)

Table 5 - Costs of cataract surgery.

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

Discussion. The lack of first-rate quality trials to synthesize 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. The data that we reviewed produced no surprises and appeared 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 2 groups, which compared favorably with those found in the US National Study of Surgery Outcomes.¹² 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 providing clinicians with a certain degree of confidence in selecting the day care approach.

Although there were statistically significant differences in immediate postoperative complications between the 2 groups, these did not appear to have a marked effect on the overall postoperative complications which should further minimize 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.

It is perceived that day care surgery should provide a more cost-effective approach in the treatment of cataract surgery, a premise, which the 2 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, which may in the end support the change solely as a cost-shifting economic exercise.

Implications for practice. This review based on one detailed and methodologically sound trial 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 inpatient cataract surgery. 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 whilst 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 programs 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 randomized trials indicates that the progression from in-patient to day care as the primary treatment modality has already taken place. In the developed world there does not appear to be any debate about the safety and outcomes of day care cataract surgery, so future research could explore the issue of cost shifting or the issue of case selection to identify which combinations of patient factors indicate a need for in-patient care.

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 also important that additional trials pay greater attention to detail in their design and reporting and consider using the CONSORT 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 patient 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 consideration should also be given to a greater role for these patient assessed visual function and visual quality of life instruments, and specifically in the measurement of need for, and benefits from surgery.

Acknowledgments. *The Cochrane Eyes and Vision Group developed and executed the electronic searches for this review. We would like to acknowledge Anupa Shah, Henry Ejere and Katherine Henshaw for their guidance throughout this review. The reviewers 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.*

References

1. Snellingen T, Evans JR, Ravilla T, Foster A. Surgical interventions for age-related cataract. In: The Cochrane Database of Systematic Reviews, 2, 2002. Art. No.: CD001323. DOI: 10.1002/14651858.CD001323. Chichester, UK: John Wiley & Sons, Ltd.
2. Kupfer C. The International Agency for the Prevention of Blindness. *Am J Ophthalmol* 1994; 7: 253-257.
3. Minassian DC, Mehra V. 3.8 million blinded by cataract each year: projections from the first epidemiological study of the incidence of cataract blindness in India. *Br J Ophthalmol* 1990; 74: 341-343.
4. Limburg H, Kumar R, Bachani D. Monitoring and evaluating cataract intervention in India. *Br J Ophthalmol* 1996; 80: 951-955.
5. Thylefors B. A global initiative for the elimination of avoidable blindness. *Am J Ophthalmol* 1998; 125: 90-93.
6. Cresswell PA, Allen ED, Tomkinson J, Chapman FM, Pickering S, Donaldson LJ. Cost effectiveness of a single-function treatment center for cataract surgery. *J Cataract Refract Surg* 1996; 22: 940-946.
7. Castells X, Alonso J, Castilla M, Comas M. Efficacy and cost of ambulatory cataract surgery: a systematic review. *Med Clin (Barc)* 2000; 114 Suppl 2: 40-47.
8. Rose K, Waterman H, Toon L, McLeod D, Tullo A. Management of day-surgery patients with cataract attending a peripheral ophthalmic clinic. *Eye* 1999; 13: 71-75.
9. Ingram RM, Banerjee D, Traynar MJ, Thompson RK. Day-case cataract surgery. *Trans Ophthalmol Soc U K* 1980; 100: 205-209.
10. Percival SP, Setty SS. Prospective audit comparing ambulatory day surgery with inpatient surgery for treating cataracts. *Qual Health Care* 1992; 1: 38-42.
11. Lowe KJ, Gregory DA, Jeffery RI, Easty DL. Suitability for day case cataract surgery. *Eye* 1992; 6: 506-509.
12. Steinberg EP, Tielsch JM, Schein OD, Javitt JC, Sharkey P, Cassard SD, et al. National study of cataract surgery outcomes. Variation in 4-month postoperative outcomes as reflected in multiple outcome measures. *Ophthalmology* 1994; 101: 1131-1140.

References to included studies:

Castells X, Alonso J, Castilla M, Ribo C, Cots F, Anto J. Outcomes and costs of outpatient and inpatient cataract surgery: a randomised clinical trial. *J Clin Epidemiol* 2001; 54: 23-29.

Galin MA, Boniuk V, Obstbaum SA, Barasch KR, Baras I. Hospitalization and cataract surgery. *Ann Ophthalmol* 1981; 13: 365-367.