Cataract Surgery Outcome in a Referral Center: Farabi Eye Hospital, Tehran; Study Protocol

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Abstract

***Purpose*:** To report a study design for assessing the cataract surgery outcome

***Methods*:** We conducted the study in an eye hospital in which over 13,300 cataract extractions are performed annually. Sampling framework and recruitment included hospital records of patients who underwent age-related cataract extraction within the preceding 5 years that were sampled randomly for 470 patients. Phone recruitment was made and the surgical records were reviewed. Novel variables were 'mature cataract rate', 'surgeon competence', 'surgically challenging eye', 'wound enlargement' and 'use of an injector to insert an intraocular lens', 'posterior capsule status', 'postoperative spectacle use', and 'unmet need'. Causal diagrams (to facilitate modeling), data mining (clustering and decision matrix), and outlier analysis were used.

***Results*:** Subjects were categorized as deceased, unavailable, or successfully contacted with the last subcategorized as participants or non-participants (declined or noncompliant), in a participants' flow chart. The participation rate was 51%. Participants and non-participants were comparable regarding baseline and surgical characteristics. The causes of visual impairment were reviewed and a standardized diagnostic scheme was developed that included eight anatomic headings and 18 disease-specific subheadings. A reporting scheme was sketched.

***Conclusion*:** Despite shortcomings in the quality and availability of the hospital and surgical records and a relatively low participation rate compared to prospective data collection, this retrospective cross-sectional approach was practical for evaluating the quality of cataract surgery in a hospital in a developing country and the protocol is recommended as a guideline to manage such a project.

***Keywords*:** Outcome Study, Cataract Extraction, Quality of Health Care, Protocol, Iran

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Introduction

"In 1999, the World Health Organization (WHO) launched 'Vision 2020: The Right to Sight', a joint initiative with the International Agency for the Prevention of Blindness, to eliminate avoidable blindness by 2020 in partnership with other United Nations agencies, governments, eye care and health organizations, institutions, professionals, and individuals".[1]

The causes of blindness and visual impairment vary according to local ecologic factors (including infectious diseases),[2,3] socioeconomic conditions,[3] the demographic factors of a population, and the availability and quality of eye care services[4] but cataract is the leading cause of blindness worldwide.[2,5,6] Although, cataract backlog may not be the prevalent cause of blindness in developed countries, it is still a leading cause of visual impairment in these communities.[7,8] The visual impairment caused by cataract is treatable through a highly cost-effective procedure,[9-11] which is why Vision 2020 advocates an increase in the rate of cataract surgery (CSR): number of cataract surgeries per million per year.[2,12]

In Iran, the cataract surgery rate has been increasing from 526 in 2000 to 1,331 in 2005, which is still less than the lower limit recommended by the WHO.[13,14] The Tehran Eye Study reported that in an urban setting about 20% of individuals 40 years of age and older had a gradable cataract, of these 0.9% was bilaterally blind.[15] Excluding uncorrected refractive error, cataract was the leading cause of visual impairment.[16]

Cataract surgery has evolved tremendously during the previous decades and has turned a largely extractive procedure into a refractive procedure with marked improvements in safety and outcome.[17,18] Unfortunately, the quality of care is not uniform globally and nationally, and merely focusing on quantity is unsatisfactory.[2] It is noteworthy that poor attention to the refractive aspects of cataract surgery even increases the refractive error burden worldwide. Quality of life is increasingly becoming a key factor in the success of health care delivery as the population ages and the lifestyle changes.[19] In Iran, the quality of cataract surgery is a top priority as far as Vision 2020 is concerned. Identification of determinants of outcome would be instrumental in improving ocular care.

In this regard, we planned a project with the following objectives: determining the current visual and refractive outcomes of cataract surgery in a major referral and teaching eye hospital in a developing country; estimating the prevalence of blindness and visual impairment in patients who had undergone cataract surgery; assessing the roles of challenging ocular features, ocular comorbidities, surgical techniques and systemic conditions on the outcome; and, evaluating the roles of quality of care, surgeon competence, and demographics on the outcomes.

The evidence is long overdue. It not only has local implications but is generalizable to similar settings.[13] We used a particular study design to achieve the above mentioned objectives. The purpose of this article was to report the details and novel aspects of the study design. Also, the current report serves as a valuable reference about the methodology in other reports of the study. It should be noted that many of the results and observations are presented separately in original articles.

Methods

Settings and design

The study was conducted in the largest university-affiliated referral eye hospital in Tehran, which has a current annual volume of about 13,300 cataract surgeries (about 40% of the hospital's total annual surgical procedures) and more than 300,000 visits. A hospital-based cross-sectional approach was used to assess the surgical outcomes in patients with an age-related cataract. The investigations were performed according to the guidelines of the Declaration of Helsinki and the institutional review board approved the study protocol.

Eligibility, sampling framework, and sample size calculation

All patients over the age of 50 years at the time of surgery between 2002 and 2007 who underwent surgery for an age-related cataract were included in the sampling framework. The patient records from the hospital's medical record system were ordered based on the

FoxPro 6.2 database (Clipper 5.2 software, code H25 of ICD-10). Patients with a history of major head trauma, ocular inflammatory disease, or previous procedures capable of inducing a cataract e.g. radiotherapy were excluded. The coding of the hospital record system also facilitated exclusions.

The postoperative presenting visual acuity (VA) was selected as the best index for the surgical outcome and quality of life to calculate the sample size. A practical range of 0 to 1.3 in logarithm of the minimum angle of resolution (logMAR) units (equivalent to $^{20}/_{20}$ vision to counting fingers at 3 meters) was adopted. The range was considered equal to five standard deviations (SDs). The estimated SD then was 0.26 [=(1.3-0)/5]. The accuracy of the estimate was targeted at 0.1 logMAR. For a 95% confidence interval for this estimate (α=0.05), the sample size was 26 or above: $n >/= (1.96^2 * 0.26^2)/0.1^2 ~= 26$

We anticipated a high degree of heterogeneity in the population. To ensure the subgroups' stable outcome, we choose three variables, i.e., surgeon competence, socioeconomic status, and surgical framwork, and considered 3, 3, and 2 categories for them, respectively. Multiplied by 18, the final sample size was 470 eyes of 470 subjects.

Recruitment

A maximum of three phone calls was planned using the contact information in the hospital records. According to a standardized note, we attempted to talk directly to the patient who underwent surgery; a flexible visit schedule was arranged. The patients were told that further diagnostic and therapeutic care would be provided if needed. Those who agreed to participate received a reminder call the day before the scheduled appointment; those who did not participate were called again and rescheduled.

Pilot study and examination protocol

We conducted a briefing session for the examining residents and optometrists, researchers, and nurses. The team members remained constant throughout the study.

A pilot study with 40 patients was carried out to grossly estimate the response rate, revise the data collection sheets, optimize the circulation of patients through the clinic, and approximately measure how long each step of visit takes time. The examination protocol and patient flow were refined.

Figure 1 shows the final patient circulation format. The patient was accompanied by the study researchers throughout each step. If a subject had difficulty responding to questions, a relative was asked for clarification. The patient records were consulted interactively to facilitate data collection at the time of the interview and examinations. An electronic database that included the information of participants and non-participants was considered to facilitate patient tracking.

The VA was measured using chart projectors (CP – 670 $^{20}/_{10}$ – $^{20}/_{400}$, Nidek Co., Gamagori, Japan) and E letters at a distance of 4 meters. The monocular VA was recorded as the smallest line at which the patient could read four letters correctly. If a person was unable to read the largest Es on the chart ($^{20}/_{400}$ Es) at 4 meters, the vision was recorded as counting fingers, hand motions, and light perception.

The causes of visual impairment were identified and appropriate follow-up was scheduled. In cases with substantial posterior capsule opacification (PCO), the patients were reexamined after YAG laser capsulotomy. In cases in which no specific cause of visual impairment was identified, pinhole VA testing, ocular imaging, and referral to a neuro-ophthalmologist was considered (Figure 1).

Novel variables

The study data collection form (Appendix I) shows a comprehensive list of the variables. The following definitions of the novel and/or complex variables were used in the study.

Presenting VA--The presenting VA was defined as the participant's habitual distance correction that was measured along with the conventional uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA).

Socioeconomic status--The socioeconomic status was determined by the patient's educational level, occupation, and residence information and combined in a model (Table 1). The ratios and coefficients were reached through the consensus of the

research group.[20] The family income was not available for this purpose.

Mature cataract rate--The presence of a white cataract (intumescent or phacomorphic cataracts) is usually documented in the hospital records. We used this, to calculate the mature cataract rate in the studied population. From a technical standpoint, mature cataract is more challenging and visual outcome is guarded, as the eye is more likely to have a pre-existing pathology, and the patient may not expect a useful vision from that eye already and do not seek care for such an eye.

Surgeon competence--We considered qualification and experience. A junior resident was considered a novice surgeon; a non-cornea specialized faculty member, a senior resident, a non-cornea specialized fellow, and a non-academic general ophthalmic surgeon were considered intermediate surgeons; and a cornea fellow and the institution's cataract surgeons with the most years of practice were considered advanced phaco surgeons. The suitability of ranks allocation was reviewed by the head of the Centers' Cornea Division.

Surgically challenging eye--These eyes included those cases with a small pupil, pseudoexfoliation syndrome, phacodonesis, surgically challenging corneal opacity, shallow anterior chamber (intumescent cataract and phacomorphic glaucoma), and a mature cataract (if phacoemulsification was performed). In the pilot study, we found that features such as a narrow fissure and deep-set eyes were not consistently recorded and thus were excluded from the scope of the study.

Surgical technique--Besides conventional extracapsular cataract extraction (ECCE) and phacoemulsification, a variant that was referred to as phacosection or small incision cataract surgery (SICS) was documented too. SICS includes features of both ECCE and phacoemulsification. Intracapsular cataract extraction (ICCE) also was documented occasionally. A surgery was considered to be "converted" when the phacoemulsification procedure was complicated and required wound enlargement and nucleus extraction (manual nucleus removal). In this way, the technique becomes similar to ECCE or SICS. The details of the surgical records were studied extensively, and the examiner verified the surgical technique based on the examination findings at the time of the study visit. Wound structure, suture scars, intraocular lens (IOL) type, and the use of an IOL injector were the clues.

Wound enlargement and injector use--These were recorded through review of the surgical record and examination (see Surgical technique above). Specifically, the internal wound edge was identified and sized using the ruler of the slit-lamp biomicroscope to verify the injector use and/or wound enlargement for IOL insertion.

Posterior capsule status--The posterior capsule status of the pseudophakic eyes was categorized as opened by YAG laser, in need of capsulotomy, clean or mildly opaque, or ruptured at the time of surgery.

Postoperative spectacle use--Participants were asked if glasses for near vision had been prescribed for them postoperatively. Following a refractive examination, an improvement in VA by more than two lines was recorded.

Visual impairment cause--Postoperative VA of the patients were ranked as optimal, satisfying, acceptable, low, and poor vision according to the cutoffs of $^{20}/_{25}$, $^{20}/_{40}$, $^{20}/_{100}$, and $^{20}/_{200}$ (equal to 0.1, 0.3, 0.7, and 1 logMAR, respectively). The examiners listed up to three (preoperative, operative, and/or postoperative) causes for visual loss in descending order of magnitude. The reasons for visual impairment for any patient were labeled according to the categories in Table 2.

Unmet need--Unmet need was defined as the need for any of the following relevant diagnostic and/or therapeutic procedures at the time of the study examination: visual field examination, fluorescein angiography and other imaging modalities, retinal photocoagulation for diabetic retinopathy, cataract surgery in the fellow eye, spectacle prescription (see Postoperative spectacles use above), YAG laser capsulotomy (see

Posterior capsule status above), missed glaucoma follow-up examination, and referral for a neuro-ophthalmologic evaluation.

Analytic considerations

The axial length and IOL power data were approached in a categorical fashion; short, normal, long, and very long axial lengths were defined as <22, 22-24.5, 24.5-26 and >26 mm for our data set, respectively. Baseline independent variables, determinants, and outcomes were organized in a causal diagram to facilitate data exploration. Decision tree and clustering (data mining) were applied to the data.

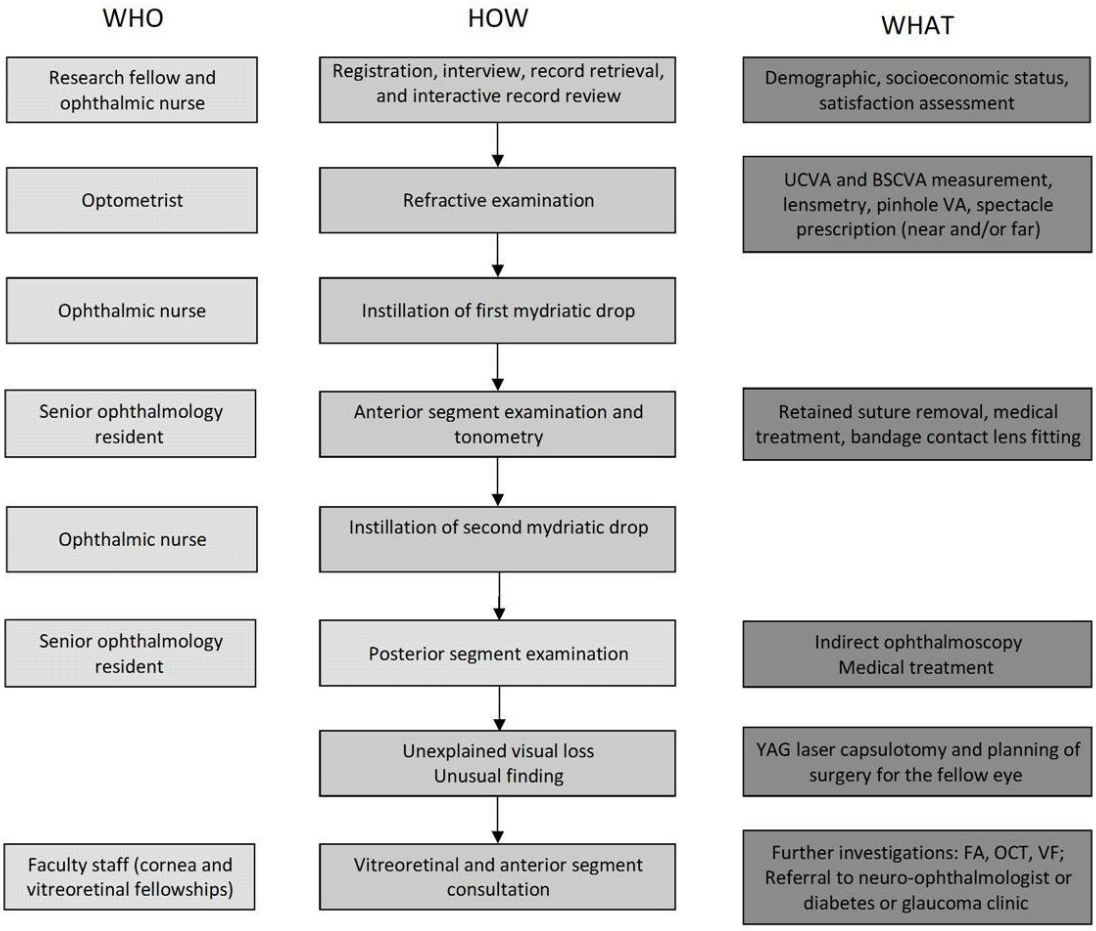

Figure 1. Examination flow chart
UCVA: Uncorrected visual acuity, BSCVA: Best spectacle-corrected visual acuity, FA: Fluorescein angiography, OCT: Optical coherence tomography, VF: Visual field

Table 1. Socioeconomic status model

Parameter	Ratio	Category	Coefficient
Education	$^{45}/_{100}$	Not having a high school diploma	0.33
		High school diploma	0.66
		College/University degree	1
Occupation*	$^{33}/_{100}$	Worker, farmer, tradesman, housewife	0.33
		Government employee, technician, policeman	0.66
		Manager, teacher, engineer, physician, nurse	1
Residence	$^{22}/_{100}$	Rural	0.33
		Urban (not Tehran)	0.66
		Tehran	1

*Either working or retired.

Table 2. Classification of causes of poor visual outcome after cataract surgery

Category	Causes
Refractive (pseudophakic eye)	(induced) Astigmatism
	Under-corrected refractive error
Corneal	Irregular astigmatism &/or opacity
IOL	Subluxation &/or tilt
	Aphakia
Posterior capsule	Opacification (PCO)
Retinal	ARMD (sub classified as dry or wet)
	Diabetic retinopathy
	Retinal vascular disease
	Pathologic myopia
	Foveopathy (epiretinal membrane, macular hole, NOS)
	Endophthalmitis or retinal detachment
Optic nerve	Atrophy
	Dysplasia
Glaucoma	(not further specified)
Neurologic &/or unexplained	Nystagmus Suspected amblyopia NOS

IOL: Intraocular lens, PCO: Posterior capsule opacity, ARMD: Age-related macular degeneration, NOS: Not otherwise specified

Results

Participation

The average annual cataract extraction rate was 11,202 (2002-2007); 2,800 records were selected randomly to fulfill the sample size, and a total of 478 patients (558 eyes) were included. Figure 2 shows the participation flow chart. The participation rate (defined as the proportion of the eyes which were examined to the total eyes of the contacted ones) was 51%. Sampled subjects who did not undergo an examination after the initial invitation were contacted during two subsequent weeks. If a subject did not attend after the third contact or refused to attend, he or she was considered a non-participant.

To assess the generalizability of the outcomes in the studied population, those who attended the examination were compared with non-participants based on seven factors (Table 3).

The mean age of participants was 67.2±8.8 at the time of operation and 48.7% of them were female. Phacoemulsification was the routine technique for cataract extraction, being performed on about 75% (n=417) of the eyes. Participants mean preoperative VA was 1.34±0.7 logMAR. Mean postoperative UCVA and BSCVA was 0.36±0.4 and 0.21±0.3 logMAR, respectively. Of the 558 operated eyes, about 27% (151 eyes) had UCVA of more than $^{20}/_{25}$, while the frequency increased to 51.8% (289 eyes) following best-spectacle correction of their VA. Only 5% of the eyes (n=28) had a UCVA less than $^{20}/_{200}$. Detailed reports on the outcome are prepared according to the reporting structure mentioned below.

Data handling and analysis, and reporting

The causes of visual impairment were studied in depth; the completed forms and records were reviewed interactively to reach the best possible diagnoses concerning the lower than expected BSCVA. The standardized diagnostic entities are shown in Table 2.

Following extensive preliminary data exploration, a reporting structure is sketched. This is a draft structure:

- The study protocol (current report)
- Cataract surgery visual outcome and the determinants: systemic conditions, ocular co-morbidities, ocular surgical features, and surgical technique;
- Residual refractive status following cataract surgery – covering spherical equivalent and cylinder, IOL power calculation, axial length, and wound features[21];
- Role of socioeconomic status, age, and gender in the outcome of cataract surgery and its postoperative care[22];
- Transition of the technique of cataract surgery in the Center[23];
- Posterior capsule opacification and its determinants[24];
- Baseline features and cataract surgery outcome in pseudoexfoliation syndrome.

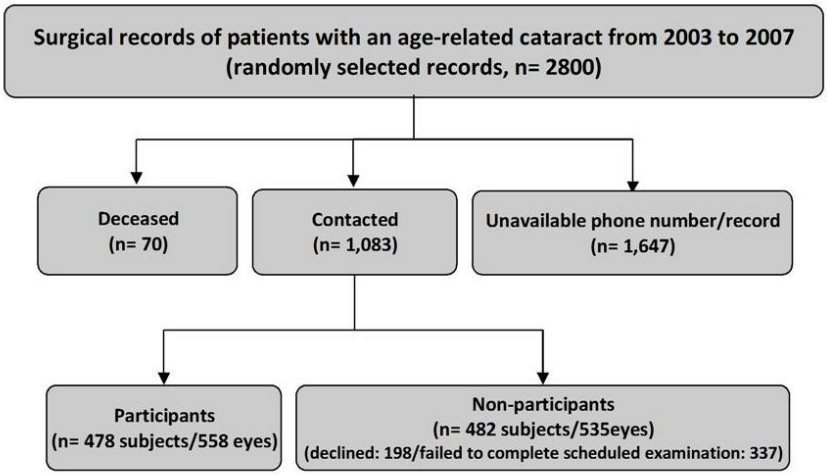

Figure 2. Participant flow chart

Table 3. Comparability of demographic and surgical features of non-participants and participants

Variable	Participants	Non-participants	P
Female, %	48.7	53.2	0.18
Mean age, y	67.2±8.8	69.1±8.4	0.007
Resident of Tehran, %	94	91	0.62
Cataract density, %			
Mature	12.5	15	0.43
Others	87.5	85	
Phaco and SICS, %	90	77	<0.001
Intraocular lens power, diopter	19.92±4.0	19.98±3.9	0.32
Aphakia, %	0.5	0.7	0.17

Discussion

Two major alternative approaches could generally be used to evaluate clinical outcomes and their determinants: a prospective observation of the outcome (clinical trial), and a retrospective evaluation of the outcome in previously treated subjects (cross-sectional and historical cohort). We used the latter in the current study and recruited patients who had previously undergone surgery in the hospital and performed a comprehensive examination and record assessment.

The advantage of this methodology is the availability of data at the present time. Ideally, this information is also accessible from an state of the art hospital information system based on regular postoperative follow-up and care data that can be analyzed. However, this is not the case for most settings in a developing country. For this reason, after record assessments, we randomly sampled the operated cases for a comprehensive outcome evaluation, which made the study more analogous to a cross-sectional, hospital-based study.

By nature, data generation in a prospective study is much less prone to selection or information bias; it is in contrast with the retrospective studies whose data must be subjected to comparability analyses and adjustments (Table 3). A prospective study better describes the baseline status, although, the picture might not be representative of the actual situation and long-term observation is needed. Clinical trials performed to determine efficacy and safety should not be confused with outcome studies despite involvement of an intervention, i.e., cataract surgery in the current study.

Despite careful definitions of the targeted variables in the pilot study, redefinition of some variables was needed after data collection because of limited heterogeneity of some variables and inconsistent documentation of the preoperative examinations. An example of the latter was the cataract density for which the following inconsistent terminology was used in the records: 'PSC', 'NS', 'moderate cataract', 'cataract', 'brunescent', 'mature', 'intumescent', and occasional grading of 1 to 4 plus. The red reflex also was not recorded consistently. For this reason, we used mature cataract rate instead. In a prospective study, a standardized system like the Lens Opacities Classification System III could be applied.[25] It is well known that the presenting preoperative VA (due to the variable baseline refractive status) and even the preoperative best-corrected VA (due to the varying effects of cataract type and morphology on vision) are not good indicators of cataract severity.

The participation rate in the current study was 51% (Figure 2). Participants were generally comparable to non-participants except for their age and the used surgical technique (Table 3). The observed difference between the participants' and non-participants' ages is not clinically significant. But we had a higher rate of phacoemulsification in participants vs. non-participants i.e. the patients who underwent phacoemulsification complied better. Analysis of non-participation is notoriously complicated; one may suggest that patients with a better outcome comply with follow-up better; conversely you may counter-argue that the patients with any kind of complication and a suboptimal outcome respond better to such recruitment. Moreover, patient experience, residence, and systemic health status affect participation.[26] Anyway, relatively low participation rate may adversely affect the generated evidence; this issue will be dealt with in the outcome report.

It cannot be overstated that the communication skills of the survey recruiters, their tone and sensitivity along with the care that the patients will receive (e.g., refractive service) are crucial for ensuring a high participation rate. These were observed in the current study.

One of the focused themes of the study was on the association of the surgeon competence with the outcome, but it remained un-resolved; as the experienced surgeons operated on the eyes that were considered prone to complications. The resultant complication rate was comparable to that of the novice surgeons.

Conclusion

In conclusion, the applied protocol in this clinical-based cross-sectional cataract surgery outcome evaluation study yielded evidence on the quality of cataract surgery. Findings have local application and may not be generalizable to other settings. But, the detailed patient circulation and examination protocol, data collection form, and the definitions of the variables and diagnostic and reporting schemes could be adopted for similar studies.

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