

Informed consent for cataract surgery—what is best practice?

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Abstract

Purpose: To test the basic knowledge of population pertaining to cataract and its treatment and to determine the best method among conventional written, audiovisual and oral presentation by surgeon for informed consent before cataract surgery.

Method: Randomized prospective study at the JN Medical College, AMU Aligarh. Patients were divided into 3 groups and pretested by a 12 point multiple choice questionnaire for baseline knowledge. They were subjected to informed consent by conventional written material or audiovisual aid along with written aid or by oral presentation by surgeon along with written and audiovisual aids respectively. Post-test by same questionnaire was taken to find out gain, retention and recall of knowledge by the patient and identify the best consent practices for cataract surgery.

Results: Of the 126 patients enrolled, 3 randomized groups of 42 each were pretested and administered informed consent. The baseline knowledge of patients was similar before consent in all three groups with mean scores at 4.5, 4.5 and 4.7 ($P>0.05$), and increased significantly after the consent process in all the groups with mean scores at 7.2, 8.2 and 9.3 out of 12 respectively ($P<0.001$). The increase in level of knowledge was maximum in Group 3 (surgeon's oral presentation with audiovisual and conventional written aids) compared to Group 1 (conventional written aid only) and Group 2 (conventional written and audiovisual aids) ($P<0.001$).

Conclusion: The significant increase in post test scores of patients after informed consent reaffirms the value of detailed consent in elective surgeries like cataract. Combination of conventional written consent with audiovisual aids and oral presentation by surgeon is the best method to administer informed consent. This will educate patients to take informed self-care decisions and can reduce healthcare services burden by postponing unnecessary surgeries and minimize negligence claims and indemnity issues.

Keywords: Audiovisual aids, Cataract surgery, Informed consent, Patient knowledge, Surgeon's talk, Written consent.

Introduction

Informed consent is a right of the patient which enables him/ her to take informed decisions about available treatment options that can be exercised, risks and costs involved and chances of successful outcomes. Informed consent was first defined by a US court in 1914, and has since evolved manifolds to its current standardized form.⁽¹⁾

Patients must be given sufficient information, in a way they can understand, to enable them to exercise their right of choice protected in law.⁽²⁾ Provision of information requires effective communication primarily by discussion. Verbal information is useful provided it is given in a slow, piecemeal manner intelligible to the patient.⁽³⁾ A busy ophthalmologist may end up with a conversation which is more of routine talk rather than an informative session, ignoring the specific needs of the patient.⁽⁴⁾ It is also very difficult to know beforehand what patients want to know about their surgery and how much and what kind of information provided before surgery is enough to say that the patient has made an informed decision.^(5,6) Written information leaflets with diagrams, model eyes, pictures and audiovisual aids play an important part in supplementing and reinforcing in-depth verbal discussions, thus allowing time for knowledge to percolate and questions to arise.^(4,5,6,7)

Information must be accurate, evidence-based, tested for comprehensibility and be relevant.^(2,8) If

patients are to be active participants in decisions about their care, information they receive must conform to agreed standards and presented in an acceptable way. This aims to help alleviate patients' fears and anxieties, build confidence to meet self-care needs and provide information to enable patients to make an informed choice.⁽⁹⁾

However patient comprehension, readability, grasp, attentiveness and understanding of the consent procedure, will all have a bearing on the final reception, retention and recall of information by the patient. Many studies have identified poor patient comprehension and recall as a major impediment to a successful consent procedures.^(10,11) Western studies have highlighted the deficiencies in the consent process to be the foremost cause of medical litigation and damages and liability payments by surgeons in cases of complications and less favorable outcomes of the cataract surgical procedure.^(12,13)

With economic growth, education, globalization, outreach and universal availability of standard eye care, provision of cataract surgery is increasing in the developing world especially India. This leads to special concern regarding the consent process as these populations may have difficulty with understanding the complex surgical concepts and are not always fully informed decision makers.⁽¹⁴⁾ The informed consent process can be especially challenging for indigent

patients in developing countries who may have limited formal education, high rates of illiteracy, and incorrect ideas about medical interventions. Compounding the problem is a lack of statutory guidelines and standardized consent procedure across a country as diverse as India.

With this backdrop, we decided to undertake a study of the informed consent process for cataract surgery to see which of the available methods fits best to the specific needs of information and exercise of choice of the population attending a Government Medical College Hospital in north India.

Subjects and Methods

This randomized prospective study was carried out at Ophthalmology outpatient department of the Jawaharlal Nehru Medical College Hospital of the Aligarh Muslim University between October 2015 to April 2016 after Institutional ethical clearance was obtained. All consecutive patients scheduled for first eye cataract surgery were eligible for participation. 126 out of 150 patients consented for participation after being invited and administered informed consent regarding the method and goals of the study. To obtain a power of 0.8 at a minimum significance level of 0.01 and a large effect size (Cohen's $d = 0.8$), each group required at least 38 patients.⁽¹⁵⁾ Exclusion criteria were previous exposure to consent procedure for cataract surgery and poor comprehensibility due to advance age, hearing disability or mental illness and unwillingness to participate. Socio-demographic data was recorded. Educational status was categorized as '0' for no schooling, '1' for primary school, '2' for secondary school and '3' for college education.

Patients were randomized to 3 groups of 42 patients each. Group A received only resident performed consent with conventional written consent material, group B received audio-visual material describing surgery in addition to written aids and group C received oral talk by the operating surgeon in addition to the written and audio-visual aids. All groups received information on cataract, its surgery, risk-benefit, complications, treatment options and consent. A basic level multiple choice questionnaire on cataract and its surgery was administered twice during the study. First test (Pretest) was undertaken immediately before the consent procedure to check baseline knowledge, the patients were subjected to informed consent and second test (Post-test) was done on the day of surgery in the preoperative room. A predesigned, pretested questionnaire was selected by extensive literature search and adopted for the study.^(4,14,16,17) Care was taken to ensure that all the questions in the questionnaire were covered in the consent information provided through either the written, audio-visual or oral aids. The written material was 5th grade in bold print and large font. The written and audio-visual aids were sourced from practice guidelines issued by Delhi Ophthalmic Society and

promotional CD by Cipla Pharmaceuticals (India) Limited respectively.

Results were analyzed using SPSS software (version 21, SPSS, Inc.) Significance was tested using ANOVA with Post Hoc test.

Results

A total of 126 patients participated in the study, randomized into 3 groups of 42 patients each. 66 male and 60 female patients were studied. Mean age was 63 years in group A, 61 years in group B and 62 years in group C. Mean education level was 1.95 in group A, 2.09 in group B and 1.95 in group C, which was equivalent to secondary school level. The participants were evenly matched for age, sex and education level and no statistically significant difference was seen.

The questionnaire was scored by the number of questions answered correctly out of 12. Responses like "I don't know" or "I don't remember" were counted as a 0 in the final score. Initial pre informed consent scores were not statistically significant in the 3 groups with mean scores at 4.5, 4.5 and 4.7 out of 12 respectively ($P > 0.05$).

Patients in all 3 groups showed significant improvement in scores between pre and post informed consent quizzes ($P < 0.001$). Within the post consent scores, the patients in group C (mean score 9.35 ± 1.28 SD) scored significantly higher than group B (mean score 8.21 ± 1.13 SD) with $P < 0.001$, and group A (mean score 7.21 ± 1.37 SD) with $P < 0.001$ on Post hoc tests. Performance on specific questions also had a generalized pattern with questions 1, 2, 3, 4 and 8 having similar scores between pre and post-test, while the other questions had significant differences in performance between pre and post-test and on Post hoc testing between the 3 groups.

Table 1

Multiple choice pre/ post Consent questionnaire. Correct answers are highlighted in bold print.

Name: _____, Age in years _____, Sex: M/ F, Highest grade of education completed: _____

- 1.) What is the problem you have?
 - A. The lens in my eye is cloudy
 - B. An object has become stuck in my eye
 - C. The blood supply to my eye is disturbed
 - D. The nerve signals between my eye and brain are disturbed
- 2.) What is this condition called?
 - A. Glaucoma
 - B. Macular degeneration
 - C. Cataract
 - D. Diabetes
- 3.) Who is at risk of developing cataracts?
 - A. People with diabetes
 - B. People who smoke

- C. People with UV sunlight exposure
 D. Increased age
 E. All of the above
- 4.) What are the symptoms of cataract?
 A. Itchiness and redness
 B. Shooting pain
 C. Flashing lights and floating objects
 D. Blurry vision, faded colours and poor night vision
- 5.) When should you consider surgery?
 A. When you lose your vision completely
 B. When daily activities are limited and I feel benefits outweigh risks
 C. After waiting for a year to see if symptoms improve on their own
 D. None of the above
- 6.) How is cataract surgery performed?
 A. Laser
 B. Small incision/ sound energy
 C. Robotic surgery
 D. None of the above
- 7.) Which of these is not a risk of cataract surgery?
 A. Bleeding
 B. Infection
 C. Loss of vision
 D. Migraine
- 8.) What do you have to remember after surgery?
 A. Place daily eye drops as directed by your doctor
 B. Avoid strenuous activity
 C. Wear a patch or dark glasses
 D. All of the above
- 9.) What are the alternatives to surgery?
 A. Eyeglasses or contact lenses
 B. Natural vitamins
 C. Leave it to heal by itself over time
 D. Eye drops
- 10.) What is the chance of serious complications?
 A. <2% (less than 2 of 100 people)
 B. 10% (10 out of 100 people)
 C. 25% (25 out of 100 people)
 D. 50% (50 out of 100 people)
- 11.) What is the chance of your vision becoming better?
 A. 25% (25 out of 100 people)
 B. 75% (75 out of 100 people)
 C. >90% (more than 90 out of 100 people)
 D. 100% (100 out of 100 people)
- 12.) What is the chance of your vision becoming poor?
 A. <2% (less than 2 out of 100 people)
 B. 10% (10 out of 100 people)
 C. 25% (25 out of 100 people)
 D. 50% (50 out of 100 people)

Table 2: Results of the questionnaire

Group(s)	Pre- Consent		Post- Consent		P-Value
	No.	Mean(SD)	No.	Mean(SD)	
Conventional written consent by resident	42	4.50(1.17)	42	7.21(1.37)	<0.001
Audio-visual material in addition to conventional written consent	42	4.52(1.31)	42	8.21(1.13)	<0.001
Oral talk by the operating surgeon in addition to the written and audio-visual aids	42	4.71(1.19)	42	9.35(1.28)	<0.001
P-Value	>0.05		<0.001		

Discussion

As paternalistic consent practices are declining, patients are in a dreadful situation of deciding on their operative choices and aftercare without any baseline medical information. Cataract surgery has this enviable position of being a relatively safe, successful surgery generally performed on otherwise healthy subjects. However this reflects in the patient's high expectations with little factual knowledge and a high sense of dissatisfaction and anguish if something goes wrong. Informed consent can go a long way in educating the patient about the procedure so as to avoid undue criticism and often legal proceedings at a later date. Cheung and Sandramouli compared the paternalistic and non-paternalistic approaches for consent and found no differences in patient knowledge, demonstrating that it is very difficult to inform patients about cataract, its surgery, complications and risks.⁽¹⁸⁾

Informed consent is easy to demand but difficult to deliver. No true standardization of the consent procedure exists. The method has to be tailor made to suit the specific patient's needs and aspirations. Written texts, pictures, diagrams, multimedia aids and one on one communication have all been utilized with varying results. Similarly, the choice of the person administering the consent is also important. Finding out the most suitable method and person to achieve maximal patient understanding and recall from a consent experience is therefore of utmost importance.

We found poor basic knowledge of cataract and its surgery in patients which expectedly increased after the consent process. Gain in knowledge and consequent test score was least with resident administered written conventional consent, intermediate with combination of conventional consent and audiovisual presentation and maximal with combination of an oral talk by the surgeon in conjunction with the written and audiovisual aids.

Scanlan et al found significantly high test scores on multiple choice questionnaire after standardized verbal consent explanation and take home written brochures in their patients as against controls. The recall decay was also significantly less in patients with both verbal consent and take home written information.⁽¹⁶⁾ Similarly Moseley et al experimented on medical school students and found maximal knowledge and recall in the group given video presentation in addition to the oral method as against those given oral presentation with or without diagrams.⁽⁴⁾ Lockey in a retrospective audit found high level of satisfaction among patients presented with verbal and written information along with picture cards, models and diagrams. The patients were also encouraged to have an interactive question answer session with the attending nurse.⁽⁹⁾ Shukla et al in a randomized study found lower grade reading material and audiovisual presentation to be significantly better than oral resident performed consent.⁽¹⁷⁾ Western authors have not found any association of consent knowledge and recall with educational status, however they have recorded significant decay in assimilated knowledge over the long waiting period for cataract surgery and suggest repeated consent interventions.

The developing world in general and India in particular present an altogether different scenario. Poor literacy, socioeconomic backwardness, rural urban divide may all play a role in the success of a consent strategy. Karan et al in a randomized study in rural, poor South Indian patients found that a verbal informed consent alone or augmented with multimedia aids significantly raised the knowledge levels. Also patients had higher recall against controls postoperatively.⁽¹⁴⁾

Another area of concern especially in an academic setting is patient's fear of getting operated by a student or trainee resident. Paternalistic consent approaches usually lack a mention of resident participation and lead to considerable patient anger and dissatisfaction in the event of a complication or a later revelation.⁽¹⁹⁾ In a

previous study we have established that patients have a preference for their surgeon to administer the consent in general and for training objectives in particular.⁽²⁰⁾

Our results can be explained by the possible lack of empathy, patience and communication skills in residents while taking consent from old, anxious and poorly educated patients. Similarly written consent forms are often boring and complicated to the patient and suffer from barriers of literacy and comprehension. Patients also tend to lose interest in higher grade reading material and generally do not refer to take home literature. Audiovisual presentation aids have high impact on patient's attention and help gain, retention and recall of complex medical knowledge as explained by cognitive theory of multimedia learning.⁽²¹⁾ Finally the knowledge, confidence, empathy and reassurance the operating surgeon brings along, develops a lot of trust and confidence in the patient who is also more respectful and attentive towards the surgeon. A tailored discussion about the individual needs, risks and benefits and an interactive one on one between the patient and the surgeon supplemented with written or audiovisual aids are the best methods of consent administration.

Our study lacks the heterogeneity of a representative population as most patients are urban or semi urban, younger and have comparatively higher educational status. This is explained by a large number of patients being drawn from serving, retired employees and their families covered by a contributory medical benefit scheme at the university. Repetition of information in two of the study groups might also have influenced the patient scores on the post test. We did not do a delayed test and therefore cannot comment on the recall decay of the information imparted by our methods.

Though we agree that no consent procedure can be error proof in discussing all possible risks and complications, we believe that a good risk-benefit consent practice will improve the patient knowledge of surgery and help patients make informed decisions. This will in turn improve satisfaction levels and reduce chances of possible litigation. Another benefit of specific importance to the developing world can be postponement of non-urgent surgeries with trial of alternatives like glasses. This would help prioritization and resource allocation to the more needy communities. We recommend using audiovisual aids by the operating surgeon as best practice for informed consent. How much strain this might put on the overburdened surgeon in a busy clinic is an area of concern, however it is ultimately the surgeon who is ethically, morally and legally responsible for the welfare of the patient.

Conclusion

Patients have poor basic knowledge of cataract. The significant increase in post test scores in patients after informed consent suggests the value of consent in elective surgeries like cataract where risks, benefits, complications and alternative treatment options must be

discussed. Combination of conventional written consent with audiovisual aids and oral presentation by surgeon is the best method to administer informed consent and would educate patients to take informed self-care decisions. A well performed informed consent can help patients postpone unnecessary surgeries and reduce the physical and economic burden on the health care delivery system. Imparting informed consent will also minimize negligence and indemnity claims against surgeons who intend well but fail to communicate with their patients.

Declaration

The authors declare that all authors have equally contributed to the manuscript. The authors have no financial interest in any methods or material used in the study.

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