

IMPACT OF INFORMED CONSENT ON DECISION MAKING FOR CATARACT SURGERY

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ABSTRACT

OBJECTIVE: The main focus of this study was to determine the decision making by patients on the day before cataract surgery and to assess to what extent the informed consent process influences the patient decision regarding consent.

METHOD: The descriptive cross sectional study was carried out at Ophthalmology unit MAYO hospital Lahore form August to December 2021. The size of obtained sample was 93. A questionnaire was distributed among general population for cataract surgery and they were asked different questions regarding preoperative information, physician-patient relationship and patient understanding of written informed consent.

RESULTS: Patient physician interrelation decision for surgery indicated that 90 patients (97%) trusted medical staff. Almost 57% patients agreed for surgery. 53.8% patients were informed and counseled about useful options of treatment and complications by physician. Within category responses about patients with or without consent information, the 60 patient without informed consent (47.6%) and 33 patients with informed consent (48.5%) responded that cataract surgery is easy procedure. Out of 60 (76.7%) and out of 33 (69.7%) patients were not worried about anesthesia procedure, 13.3% and 78.8% respond that there was risk of complication undergoing surgery.

CONCLUSION: Informed consent updates significantly about cataract surgery procedure, risks of complications, concept of consent form and doctor counseling about cataract surgery. Informed consent did not significantly influence the decision for cataract surgery.

KEYWORDS: Cataract, cataract surgery, informed consent, patient decision

INTRODUCTION

Cataract is the main cause of non-refractive blindness that is preventable as well as treatable. Extensive approaches to raise cataract surgery rates tends to be imperative, comprising top quality supportive client education.¹ Whereas senile/ age related cataracts develop gradually, yet cataract surgery ultimately needs to be done upon elderly population.² Earlier researches actually revealed that the surgical informed consent procedure ended up being efficient in decreasing patient's anxiety, hence; showcasing the necessity to enhance the pre-operative assessment.³

Permission is an essential requirement before every study that includes human being as a

participant for survey. Getting permission contains guidelines for the participant about his or her rights, motive of survey, methods of treatment to be undertaken, insecurity and satisfaction of taking part in survey, supposed period of survey, degree of privacy of individual detail and socio-demographic information.⁴

Participant in the survey must take part freely just after giving permission based on the guidance provided. Survey contract must attain high satisfaction for society, clinical and technical principle, be participant to freely discuss, admire participant courtesy, and respect the principle of informed consent such as Autonomy, beneficence,

non-maleficence and justice. Preoperative permission preparation may include an appointment with an optometrist, an observance of an educational video clip about educational written information etc. Client then selects either an in person session making use of their physician in clinic or telemedicine appointment for their conversation to provide consent.⁵

Informed consent forms an important component of autonomy and independent decision making in health related procedures. It involves knowledge, exposure, non-mandatory option, and decision making capacity. Capacity can be described as the potential to realize and to know purpose by decision making procedure so that logical option can be determined about whether or not agreements for medical care are given.⁶ Three fundamental criteria are essential for Informed medical consent. Firstly, the patient must be skilled; secondly he or she must be informed properly of all the procedures, impacts, benefits and potential side effects and thirdly, never coerced.⁷

Most of the challenges mentioned here may be avoided by the use of Patient Decision Aids (PDAs). PDAs current evidences in regards to the person's problem, lower the procedure that is decision-making apparent, as well as number the features of current choices (for example. advantages, harms, particular indications etc. Across scores of health specialties, choice aids boost patients' information, precision of values, part in decision making, and precision of threat insights, without any adverse effects on health consequences. These supports, in combination with (but perhaps not in place of) health expert advising, help patients recognize their choices and standards of healthcare they might receive, with options for them to decide on their own.⁸

Informed consent has now become an essential and legal requirement for all sorts of treatments and regimens in healthcare but particularly in

invasive procedures. Discussion with the client gives the physician a chance to exchange views about the patient's apprehensions, knowledge, misconceptions and sometimes inadequacies for decision making. The physician's interaction with the client is a fruitful option as it makes the patient comfortable and knowledgeable about the treatment options and their respective advantages and disadvantages so that he or she can choose the best one.⁹

Awareness of the patients by their active pre-operative participation, especially in newer procedures, can improve their satisfaction rates and also minimize need for specialized eye care.² Recent study determined that a better level of patient satisfaction can be achieved if the consent obtaining procedure includes a data pamphlet in addition to the usual face-to-face discussion.¹¹ Previous studies revealed that the application of the patient choice method might enhance the number of patients, but sometimes it might also decrease the acceptance of businesses. However this proportion is quite small.

To best of our knowledge, Impact of informed consent on decision making for cataract surgery has not been studied in Pakistan. Therefore, in this study we examined, on the day of admission before operation deas of patients, their information about treatment options and complications during surgery and their decision for operation and to what degree this information influence their decision for operation.

MATERIALS AND METHODS

The study was performed at the Mayo Hospital Lahore, College of Ophthalmology and Allied Vision Sciences King Edward Medical University, Pakistan. The descriptive cross sectional study was carried out. A consecutive series of 93 patients aged between 25-40 years who were scheduled to undergo cataract surgery was asked to participate in a study about informed consent. Who fulfill the inclusion criteria, Patients who had previously had eye surgery, mentally retarded patient, non-cooperative people were excluded,. A

written informed consent document was established and used as a template for our standardized informed consent procedure. The written information included an explanation of the word cataract; the method of surgery (ie, phacoemulsification with posterior chamber lens implantation); the risks, including an estimation of their likeliness; the postoperative period; possible refractive outcomes and the rate of surgical success; and alternatives. We explained all medical expressions using layperson's terms. Informed consent was then documented, and the patients signed the form.

A self-designed questionnaire was distributed among general population for cataract surgery, and they were asked different questions regarding preoperative information, physician-patient relationship, patient understanding of written informed consent and the patient's decisions. All the data were entered and analyzed using Statistical Package for Social Science (SPSS Version 25.00). All data were compared by applying chi square test. All data were indicated with significance level of 95%.

RESULTS

This study shows that 60 patient without informed consent (47.6%) and 33 patients with informed consent (48.5%) respond that cataract surgery is easy procedure. The results were significant as shown in (Table 1). Out of 60 (76.7%) 33 (69.7%) patients were not worried about anesthesia procedure Out of 60 (13.3%) patients 33 (78.8%) patients respond that there was risk of complication undergoing surgery. Regarding trust in medical staff and decision making, Out of 60 participants 33 patients (66.7%) said that informed consent did not influence on decision. Regarding patient understanding about informed consent, Out of 60 patients 33 patients said that they were agreed to operation. Regarding doctor counseling, out of 60 patients (56.7%) were not informed and out of 33 patients (48.5%) said that they were informed by physician about alternative treatment and complication about surgery. t. Similarly regarding influence of informed consent on decision making and Confidence about decision, out of 60 patients (75%) and out of 33 patients (99.9%) said that counseling given by physician did not influence on decision making (p=0.07) and 80% out of 60 and 84.8% out of 33 patients were confident

(p=0.78) about decision for cataract surgery.

Table 1: Category based responses of cataract patients (N=93)

	Responses	Without informed consent	With informed consent	Total	p - value
Difficulty of Cataract surgery procedure	Easy	28(46.7%)	16(48.5%)	44(47.3%)	0.05
	Difficult	27(45.0%)	9(27.3%)	36(38.7%)	
	Very difficult	1(1.7%)	0(0.0%)	1(1%)	
	Don't know	4(6.7%)	8(24.2%)	12(12.9%)	
Worried about Anesthetic procedure	yes	7(11.7%)	7(21.2%)	14(15.1%)	0.45
	no	46(76.7%)	23(69.7%)	69(74.2%)	
	Not much	7(11.7%)	3(9.1%)	10(10.8%)	
Risks of complications of cataract surgery	Yes	8(13.3%)	26(78.8%)	34(36.6%)	<0.01
	No	3(5%)	0(0.0%)	3(3.2%)	
	Don't know	49(81.7%)	7(21.2%)	56(60.2%)	
Trust in medical staff and decision making	Yes	41(68.3%)	21(63.6%)	62(66.7%)	0.94
	No	16(26.7%)	10(30.3%)	26(28%)	
	Don't know	2(3.3%)	1(3%)	3(3.2%)	
Patient understanding about informed consent	It is formality	1(1.7%)	0(0.0%)	1(1.1%)	<0.01
	It protects doctor legally	6(10%)	0(0.0%)	6(6.5%)	
	It shows I have agree to have operation	32(53.3%)	21(63.6%)	53(57%)	
	All of these	1(1.7%)	8(24.2%)	9(9.7%)	
Doctor counseling about cataract surgery	Yes	14(23.3%)	16(48.5%)	30(31.2%)	0.04
	No	34(56.7%)	2(6.1%)	34(38.5%)	
	Yes but not enough	12(20.0%)	15(45.5%)	27(30.0%)	
	Not much	45(75%)	30(90.9%)	75(80.6%)	
Influence of informed consent on decision making for surgery	Very much	13(21.7%)	2(6.1%)	15(16.1%)	0.07
	Not at all	2(3.3%)	0(0.0%)	2(2.2%)	
	Very confident	49(80%)	28(84.8%)	76(81.7%)	
Confidence about decision for cataract surgery	Not confident	1(1.7%)	1(3%)	2(2.2%)	0.78
	Don't know	10(16.7%)	4(12.1%)	14(15.1%)	
	Total	60(100%)	33(100%)	93(100%)	

DISCUSSION

Informed consent is morally and legally essential earlier to invasive medical and operation procedures. Informed consent occurs when patient-clinician communication results in a patient's authorization to undergo a specific medical intervention.¹³ This authorization is applied when the participant has ability for giving permission, for discussion about all related information and for communication about decision for surgery.¹⁴ Therefore, this study was carried out to investigate the basic view of patients, their decision making process, and to what level the patient permission process influenced their decision for surgery on the day of admission before surgery.

A previous survey which was conducted in the form of questionnaire was sent to clinical psychologist, lawyers and ophthalmologists having a sample size of 73 underwent standardized informed consent procedure. Participants responses showed that 28 (40%) patients came for surgery without any guidance; 16 (23%)

believed that there were surgical procedures without complications; and 53 (76%) estimated that there were no risks for cataract surgery. A physician dominated decision for surgery was preferred by 13 patients (44%); 16 (26%) wanted to decide together with their ophthalmologists. The possible risks of sight threatening complication did not influence 54 patients (77%) decision, and 55 patients (78%) said the patient permission did not influence their decision. The remaining 15 (22%) stated that the informed consent process positively influenced their decision.¹⁵

In advanced countries such as Europe and the United States, the courts have stated that the day before surgery is an ideal time to obtain informed consent. However, Leydhecker et al¹⁶ have indicated that 36% of participants would have preferred hearing the information at the time that their surgery was scheduled; 65% would have liked it at least a few days before the surgery. In our study, 53.8% out of 93 patients had some information mostly from their ophthalmologist, friends and family before for cataract surgery. Our findings are in agreement with the Leydheckerss, and we thus believe that patients can better be reached by providing sufficient information earlier.

The patient permission and guidance about cataract surgery was done in the survey study to evaluate patient anxiety. Results showed that few participants understood what cataract was and some had knowledge what surgery included. 48% believed that cataract surgery had no risk. In total, 80% of patients undergoing second eye surgery believed that it was completely risk-free. Average anxiety visual analogue scores (VAS) for cataract surgery were low (2.89). The second examination showed that 39% patients had accurate information about cataract, 28% knew what surgery included and 43% got the wrong notion that surgery had no risks. All patients undergoing second eye surgery thought that it was risk-free.¹⁸

In our study, 47.3% participants estimated that the cataract surgery is harmless and 38.7 % participants were not worried at all about surgery procedure. 55.5% participants believed that their surgery was risks free. In this study, the 60 patient without informed consent (47.6%) and 33 patients with informed consent (48.5%) respond that cataract surgery is easy procedure.

In present study, the 74.2% participants were not worried about anesthetic condition during surgery. 55.9% patients believed that participants believed that they would have loss of vision without surgery. 55.5% participants estimated that there were no risks for their surgery. Within category responses about patients with or without consent information, the 60 patient without informed consent (47.6%) and 33 patients with informed consent (48.5%) respond that cataract surgery is easy procedure. Out of 60 (76.7%) and out of 33 (69.7%) patients were not worried about anesthesia procedure.

CONCLUSION

Informed consent updates significantly about cataract surgery procedure, risks of complications, concept of consent form and doctor counseling about cataract surgery. Informed consent did not significantly influence the decision for cataract surgery. In this survey, participants had a fair knowledge of informed consent regarding their professional roles and responsibilities. But public awareness regarding informed consent should be done at higher levels as majority of the respondents declared that scope of informed consent on decision making for cataract surgery should be clearly defined and expanded.

RECOMMENDATIONS

Our study recommended that further detail study is required to analyze other aspects related to study on a randomized, controlled trial of video supplementation on the cataract surgery informed consent process and enhancing patients' understanding regarding several components of the informed consent process for surgery and clinical research.

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