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ANALYSIS OF THE INFLUENCE OF CLINICAL AND DEMOGRAPHIC FACTORS ON THE UNDERSTANDING OF CATARACT INFORMED CONSENT

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Abstract: Purpose: To estimate the influence of clinical and demographical information in the understanding of cataract surgery informed consent, identifying less understandable areas. To assess informed consent document concept. Methods: Multiple-choice questionnaire was designed to collect information and to evaluate the understanding of cataract surgery and informed consent. An ordinary regression model was adjusted to express the effect of clinical and demographic variables to the questionnaire score. Results: The study comprised 180 patients. Sex (female, p=0.404), non-ophthalmologist source of information (p=0.397), previous surgical history (p=0.571), not having a companion (p=0.396) nor the days since the signing of informed consent form (p=0.535) had no influence in the understanding of cataract surgery informed consent. Age (r=-0.083, p<0.001) and educational level (secondary studies r=1.845, p<0.001; tertiary studies r=4.289, p<0.001) showed statistical significance with greater strength of association educational level (OR secondary studies = 6.33, OR tertiary studies = 72.86) than age had (OR = 0.92). Conclusion: Patient's knowledge about cataract informed consent is influenced by age and educational level. The purpose and the risks, consequences of not performing surgery and postoperative indications are the least understood topics. Informed consent is seen as a forced legal obligation.

Keywords: autonomy, cataract, ethics, informed consent, legality, paternalism

Análisis de la influencia de factores clínicos y demográficos en la comprensión del consentimiento informado de cataratas

Resumen: Objetivos: estimar la influencia de la información clínica y demográfica en la comprensión del consentimiento informado de la cirugía de cataratas, identificando áreas menos comprensibles. Evaluar el concepto de "documento de consentimiento informad". Métodos: el cuestionario de opción múltiple se diseñó para reunir información y evaluar la comprensión de la cirugía de cataratas y el consentimiento informado. Se ajustó un modelo de regresión ordinario para expresar el efecto de las variables clínicas y demográficas en la puntuación del cuestionario. Resultados: El estudio abarcó 180 pacientes. Sexo (femenino, p = 0.404); fuente de información no oftalmológica (p = 0.397); historial quirúrgico previo (p = 0.571); no tener acompañante (p = 0.396), y los días desde la firma del formulario de consentimiento informado (p = 0,535), que no tuvo influencia en la comprensión del consentimiento informado en la cirugía de cataratas. La edad (r = -0.083, p <0.001) y el nivel educativo (estudios secundarios r = 1.845, p <0.001; estudios terciarios r = 4.289, p <0.001) mostraron significación estadística con una mayor fuerza del nivel educativo de asociación (OR estudios secundarios = 6.33, OR estudios terciarios = 72.86) que la edad (OR = 0.92). Conclusión: El conocimiento del paciente sobre el consentimiento informado en cirugía de cataratas está influenciado por la edad y el nivel educativo. Los temas menos entendidos son el propósito y los riesgos, las consecuencias de no realizar la cirugía y las indicaciones postoperatorias. El consentimiento informado se considera una obligación legal forzada.

Palabras clave: autonomía, catarata, ética, consentimiento informado, legalidad, paternalismo

Análise da influência de fatores clínicos e demográficos na compreensão do consentimento informado para cirurgia de catarata

Resumo: Objetivo: Estimar a influência de informações clínicas e demográficas na compreensão do consentimento informado para cirurgia de catarata, identificando áreas menos compreensíveis. Avaliar o conceito do documento de consentimento informado. Métodos: Um questionário de múltipla escolha foi desenvolvido para coletar informações e avaliar a compreensão sobre cirurgia de catarata e de consentimento informado. Um modelo de regressão ordinária foi ajustado para expressar o efeito das variáveis clínicas e demográficas no escore do questionário. Resultados: O estudo envolveu 180 pacientes. Sexo (feminino, p=0,404), fonte de informações não oftalmológica (p=0,397), história cirúrgica prévia (p=0,571), não ter um/a companheiro/a (p=0,396) nem os dias desde a assinatura do formulário de consentimento informado (p=0,535) tiveram influência na compreensão do consentimento informado para cirurgia de catarata. Idade (r=-0,083, p<0,001) e nível educacional (estudos secundários r=1,845, p<0,001; estudos terciários r=4,289, p<0,001) mostraram significância estatística, com maior força de associação para o nível educacional (OR estudos secundários = 6,33, OR estudos terciários = 72,86) que para a idade (OR = 0,92). Conclusão: O conhecimento do paciente sobre o consentimento informado para cirurgia de catarata é influenciado pela idade e nível educacional. O objetivo e os riscos, consequências, de não fazer a cirurgia e as indicações pós-operatórias são os tópicos menos compreensíveis. O consentimento informado é visto como uma obrigação legal compulsória.

Palavras chave: autonomia, catarata, ética, consentimento informado, legalidade, paternalismo

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Introduction

Cataract surgery is the most frequently performed surgical intervention in ophthalmology*(1)*. Surgical advances have increased the safety and the refractive outcomes of the procedure. Nevertheless, sight-threatening complications can happen and must be thoroughly explained to the patient*(2, 3)*.

Since cataract surgery is an elective surgical procedure, the ophthalmologist has the legal and moral obligation to respect the right of the patient to decide and for this, the patient must have a fully informed conversation with the doctor despite the pressure on medical assistance, the asymmetry of the relationship between patient and physician, the lack of time or the difficulties in assessing the individual patients' needs*(2)*. In this sense, the utility of the use of complementary material to the informed consent process is a widely accepted fact*(4-14)*, offering patients added benefits to the knowledge, such as more time to ask questions to surgeons related to specific doubted or unknown concerns, or the possibility of stopping and retaking complementary information when the patient is willing to*(1)*.

Nonetheless, medical misunderstandings and legal disputes happen to forget that informed consent has also to be about what the patients' need and special circumstances are, the levels of anxiety involved, the abilities of the patients to cope with bad news, and most importantly, how the patients understand the information provided*(15)*. Undoubtedly, good communication with patients can decrease liability risk*(3)*, but definition of adequate and sufficient patient understanding of surgical overall remains controversial*(16)*.

Thus, we were interested in determining how effectively informed consent is currently administered; the areas in which we should emphasize the explanation and the variables interrelated with the patient's understanding of cataract information through the development of an ordinary regression model.

Methods

Study Design

This transversal descriptive single-center study (Hospital Universitario y Politécnico La Fe, Valencia, Spain) recruited patients diagnosed of cataract as the only ophthalmologist pathology. All the research and data collection followed the tenets of the Declaration of Helsinki, and the local ethics committee approved the study. Patients received standardized verbal and written explanation of all required information regarding cataract surgery and after they had reported adequate understanding of the surgical procedure, they were asked to sign the informed consent form*(17)* translated in supplement 1.

Exclusion criteria for the present study included best-corrected visual acuity in the better eye worse than 0.1 Snellen, severe cognitive disability that hinders the comprehension of the informed consent of cataract surgery as well as the informed consent and the multiple-choice questionnaire of this study; age under 18 years and history of previous eye surgery. In case of not filling exclusion criteria, patients provided informed consent to participate in the study before their enrollment and once they had agreed to participate, they had an appointment before cataract surgery to answer a multiple-choice questionnaire (supplement 2) with 12 questions that sought to assess the understanding of the information received in the informed consent process and the concept that the patient had about informed consent. At the end of the survey, those incorrect concepts would be reviewed to clarify them.

Ophthalmologists who diagnosed cataract and explained verbal and written informed consent form, were different from the ophthalmologists who interviewed patients and were blinded to the questionnaire. The explanation of the surgery and signature of the informed consent was carried out the same day. People who carried out the statistical analysis were blinded to the assessment of predictors for the outcome, having masked the predictors.

A multiple-choice questionnaire was developed using questions from different existing questionnaires*(1, 6-9, 18)* and also contained answers extracted literally from the informed consent document handed in and signed by patients. Total score resulted from the sum of the questions correctly answered.

It was considered appropriate to evaluate the knowledge of the patients through a multiple-choice questionnaire because it is easier for elderly people, since the recognition of a correct answer among se-

veral is less difficult than having to write responses. Questions with figures and quantities were avoided, centering the questions in concepts.

Patients had to report their age, sex, highest educational level, if they had searched another non-ophthalmologist source of information, history of previous surgery, the existence of a companion at the time of informed consent and days since the signing of the informed consent to determine whether these factors had an influence on patient understanding. Educational level was categorized in primary studies (up to 12 years), secondary studies (up to 18 years) and tertiary studies (after 18 years). Patients were asked about cataract supplemental information to confirm non-ophthalmologist sources (general practitioner, optician, family, friends, internet…). Demographic and clinical information reported by the patients was contrasted through the clinical history.

Outcome Measures

The primary study objective was to investigate whether patient understanding about informed consent and relevant topics such as symptoms of cataract, surgery procedure, risks, complications or postoperative period was associated with variables such as age, sex, educational level, previous non-ophthalmologist information about cataracts, history of previous surgery, days since the signing of the informed consent and the existence of a companion at the time of informed consent. Secondary objective included the identification of less understandable areas of informed consent knowledge and an assessment of the concept of informed consent.

Statistical Analysis

The sample size was calculated using the Precision Efficacy Analysis for Regression (PEAR) procedure*(19)*, establishing a population estimate of 0.8, 12 predictors and a tolerance of 0.03.

The data was summarized by means, standard deviation (SD), median and 1st and 3rd quartiles in the case of numerical variables; and by the absolute and relative frequency in the case of qualitative variables. To characterize the profiles of the patients, and ordinal regression model was adjusted with the total score obtained in the questionnaire. All estimates included a 95% confidence interval with a p-value less than 0.05 to be considered statistically significant. Analyses were performed using the statistical computer program R (version 3.5.2).

Results

Patient Characteristics

A total of 180 patients were included in the study during a period of 6 months (from 1st December 2018 to 31st May 2019). Table 1 shows the distribution of the patients' characteristics.

Patient Knowledge

The average score of the total sample was 4.18 ± 2.04 SD. Table 2 shows the distribution of the answers of each question in the survey.

To study the association between the total score obtained in the questionnaire and the variables of interest (age, sex, educational level, non-ophthalmologist information, surgical history, attending accompanied/alone at the informed consent, and time since the signing of the informed consent document) an ordinary regression model was adjusted. The result of the model was expressed with the effect of the variables (Odds, Ratio, OR), its 95% confidence interval and the p-value (table 3).

No evidence was found in the association between the total score obtained with sex (female, p=0.404), non-ophthalmologist source of information (p=0.397), previous surgical history (p=0.571), not having a companion in the informed consent (p=0.396), nor the time (days) since the signing of the informed consent form (p=0,535).

The variables in which a statistically significant effect was found were age (years, p<0.001) and educational level (both up to 18 years and after 18 years, p<0.001). The results of the model were inversely related to the total score with age (-0.083), while the relationship between the total score of the survey and the educational level was direct, having a greater weight the higher the level educational of the patient (secondary studies = 1.845, tertiary studies = 4.289).

The results of the model point to a relationship between the total score and the age with a lower strength of association (OR=0.92) than the relationship

established with secondary studies (OR=6.33), which is still weak compared to those who achieved tertiary studies (OR=72.86).

Discussion

To our knowledge, this is the first study with a large sample of patients (180 patients) that uses an ordinary regression model to assess the influence on the patients' cataract knowledge informed consent of parameters such as age, education, the existence of surgical history, sex, sources of information on the surgery other than the ophthalmologist or be accompanied in the signing of the informed consent.

We have shown that age and educational level are the only variables of the model that have a statistically significant correlation with the level of patient knowledge. We did not find statistical significance with time, signing of informed consent, sex, non-ophthalmological sources of information, surgical history or accompaniment in informed consent. Additional non-ophthalmologist source for cataract surgery information and be accompanied in the hospital at the doctor's informed consent had never been tested as an influence in patients' knowledge about cataract surgery informed consent.

These findings are in line with studies that support the hypothesis of age as a limiting factor in patient knowledge about cataract surgery*(20)*. Wollinger *et al.(5)* demonstrated the inverse relationship between age and the understanding of informed consent (r=-0.18 in the study group; r=-0.06 in control group). However, in the same study, the correlation between educational level and comprehension of informed consent could not be proven (r^2=0.1 and p=0,06 in study group; r^2=0.06 and p=0.49 in control group). For their part, Tipotsch-Maca *et al.(6)* showed a slightly negative correlation between patient age and cataract knowledge (r=-0.252, p=0.005).

However, Shukla *et al.(7)* could not demonstrate the statistically significant influence of age or educational level (p>0.05) in cataract informed consent. Baenninger *et al.(21)* did not find any age-related effect in terms of knowledge retention, although authors confess their patients were younger (35.3 ± 9.6 years) than the average cataract population.

Meanwhile, Scanlan *et al.(8)* could not show more than a reverse trend (r=-0.16) of age and recall of informed consent, without showing a statistically significant association (p=0.10). However, the correlation between age and the domain of basic terminology and nature of consent (r=-0.34) reached statistical significance (p<0.01). The level of formal education was not a determinant in the recall of informed consent score. Unlike our results, Scanlan *et al.(8)* demonstrated the statistically significant trend towards memory decay over time in areas related to recall of specific risks and numerical details (p=0.004).

Like our results, Morgan *et al.(18)* demonstrated a significant correlation (p<0.01) between increasing age and a decreasing rate of retention of information. They also found significant differences (p<0.01) according to school education. Supporting our results, they also did not find differences according to sex.

Unlike our results, Erraguntla *et al.(22)* did not find a relationship between the educational background and the parental comprehension for pediatric cataract surgery (p=0.096). Zhang *et al.(10)* did not find significant differences either, according to age groups, educational background or gender groups (all p<0.05).

The general results of the questionnaire reveal bad knowledge about informed consent and cataract surgery concerns with an average score of the total sample of 4.18 ± 2.04 SD, which supports the idea of a low percentage of information retained by patients*(4, 11, 18, 23)*. Nevertheless, patients usually accept surgery with their pros and cons since they are motivated, as referred by other investigations*(18)*. The fact that cataract surgery is seen as a relatively easy procedure*(24)* influences on patients, who tend to overestimate their level of understanding*(16, 22)*. The question that arises is whether patients are conscious and therefore consistent with the decision taken. Few papers*(6, 22, 24, 25)* point to the phenomenon of cognitive dissonance as a psychological argument that would explain this bad average score, since the mental stress generated by the cataract informed consent could limit or relativize the memories related to this information (especially complications) causing selective perception and processing of information. Moreover, Falagas *et al.(16)* comment in their review the usefulness of a patient's trusted person (relative or friend) during

the informed consent not only as an emotional support, but also in improving the understanding of the information offered, which has not been demonstrated in our study (p= 0.396).

In relation to patient information about emergency surgical debridement and with a statistical approach similar to our study, Lin *et al.(12)* designed a linear regression model to study the impact of an educational video attending to different covariates. As in our study, they found that younger age (r= -0.161, p<0.05) was a significant factor predicting increased patient knowledge and understanding. Unlike our results, they obtained a non-significant education level-associated effect (r=4.021, p>0.05).

In the case of the study of Lattuca *et al.(13)* about patient information related to coronary angiography, the multivariate analysis identified as predictive factors of higher information the use of an educational video (OR 2.22, p<0.001), a higher level of education (OR 2.13, p<0.001) and younger age (OR -0.05, p<0.001).

Rosenfeld *et al.(14)* designed a study to assess the use of visual aids in the informed consent of appendectomies in children. Multivariate analysis on post-secondary education (OR 2.7, p<0.01) and use of visual consent (OR 4.0, p<0.01) were related to a better parent/guardian comprehension. Unlike our results, external resources to look up appendicitis demonstrated improved comprehension (OR 2.0, p=0.02). However, as in our study, the parent/guardian gender did not have statistical significance (p=0.87).

These results, associated with the understanding of information in other surgeries (not only in cataracts) highlight the importance of the doctor's adaptation to the patient's profile, where age and education level have showed a significant relevance in several studies.

Cheung *et al.(26)* showed that repetitive explicit counseling accompanied by the use of informed consent forms appeared to have little effect in improving patient recall of informed consent, with low proportions of patients able to describe correctly what a cataract was (39%), what cataract surgery entailed (28%) or risks associated (57%). These poor results were also surprising when observing that those patients who were operated on cataracts for the second time scored worse than those who were operated for the first time. In a similar way, the patients in our study with a surgical history did not demonstrate a greater understanding (p=0.571). It is therefore, as the authors*(26)* themselves indicate, that patient recall and understanding do not necessarily correlate, since reasoned decisions can be made without being able to recall the bases of such reasoning.

Recently, Zhang *et al.(4)* showed the long-term effect that video supplementation in cataract informed consent surgery achieved with greater retention of information on the day of surgery (p<0.01) and in the first postoperative week (p<0.01), with no differences at the preoperative moment (p=0.07). The tendency to the greatest benefit of the visualization of the video was observed in older, low education and low health literacy populations.

Examining the answers of the questionnaire of our study, we found that the question about informed consent document was correct only for 8.33% of the sample. The majority answer was chosen by half of the respondents, arguing that although they did not completely agree with the fact that "*the surgeon forces the patient to sign*", they were aware that without signing the document, the surgeon would refuse to operate them.

The only question of the survey that was unanimously correct by the patients was the one referred to the diagnosis of the disease. Another aspect quite dominated by patients is the recognition of cataract symptoms, with 36.11% of the respondents. The other aspect widely understood by the sample of patients (70%) was to recognize surgery as the only treatment for cataracts.

Approximately 40% of patients understand that the cataract is in the lens, and just over 43 % of patients understand that is caused by the loss of transparency. In both questions, the main confounding factor is the cornea, reaching up to 45% of patients who think that the cataract is caused by the loss of transparency of the cornea. Just over a tenth of the respondents (11.67%) understood that the restoration of the patient's vision was conditioned by the existence of other associated ocular diseases.

The risks related to the operation, the anesthesia and consequences of not operating are one of the most widely discussed and personalized sections in the informed consent of any operation. Vision loss is the only consequence for many of the patients (61.67%) when they were asked what could happen if they were not operated, ignoring other risks such as increased intraocular pressure, eye inflammation or increased surgery difficulty and risk of complications when postponing surgery. According to other studies*(6, 8, 11, 20, 22, 24, 25)*, patients perform poorly when asked about specific risks, although numerical outcome probabilities were not queried in our study. Besides the low memory of the risks, Morgan *et al.(18)* also highlight low recall in relation to postoperative cares in their study, and in the review carried out by Falagas *et al.(16)* the risks of the proposed surgical intervention and the benefits derived were the most unawareness areas to patients.

Assessing the content of the informed consent document used in this study (supplement 1), according to Brown *et al.(27)*, we find it offers information related to diagnosis, prognosis and treatment options (including no treatment). Information about the procedure includes its purpose, likely benefits, what to expect after the procedure and the common as well as serious effects that may occur. There is no mention to the costs of the procedure (which can be justified since it is the National Health Service without direct cost to the patient). No mention is made on how to prepare for it, what to expect during the procedure or lifestyle changes required.

Unlike in Brown's *et al.* study*(27)*, our document mentions that there is a risk of losing the eye. However, quantitative information about outcome probabilities and risks are scarce with only a figure related to the probability of expulsive hemorrhage and intraocular infection (*"less than 0,4%"*), even though it should be noted that recall decreases with increasing amounts of complex medical information*(22)*.

Among the limitations of our study, it is worth mentioning the impossibility of measuring the time dedicated to each patient. It is a factor taken as a result of interventional studies due to its importance in the real clinical practice*(21)*. Another limitation is the absence of a validated and standardized questionnaire, so we design one according to the published papers*(1, 6-9, 18)*. As Bhambhwani *et al.(11)* point out the information document used could have been more engaging with figures and illustrations, besides minimizing medical slang to the maximum.

As a conclusion, the informed consent process is usually closed with the patient's signing, without checking the information understood by the patient. In our study, age and educational level are the main patient variables to be taken into account in the informed consent process. Main topics least understood by patients are the purpose of the surgery, the risks, the consequences of non-performing surgery as well as care and postoperative indications. Finally, it highlights that patients take the informed consent document as a mandatory procedure for surgery, rather than as a document that reflects the therapeutic alliance between doctor and patient. More studies are needed to validate these results and to delve into the clinical, legal and ethical aspects of the informed consent.

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Table 1- Characteristics of the study group

		Mean (SD) / n (%) Median (1st, 3rd Q)
Age (years)		74.21 (8.99) 73.5 (68, 81)
Days since the sign of the informed consent		51.46 (31.38) 48 (26.75, 73.25)
Sex	Men	65 (36.11%)
	Women	115 (63.89%)
Level of literacy	Primary studies	114 (63.33%)
	Secondary studies	47 (26.11%)
	Tertiary studies	19 (10.56%)
Previous non-ophthalmological sources of information	Yes	102 (56.67%)
Previous surgery	Yes	151 (83.89%)
Accompanied in the informed consent	Yes	130 (72.22%)

Table 2- Percentages of answers of the study group (correct answers in **bold**)

	A	B	C	D	E
Which of the following statements do you think best defines the informed consent document?	4.44%	21.11%	50%	16.11%	**8.33%**
Which illness/problem do you have?	**100%**	0%	0%	0%	0%
In which part of the eye is the illness/problem?	**40.56%**	31.11%	21.67%	4.44%	2.22%
Which of the following symptoms is less related to cataracts?	1.67%	28.33%	13.89%	**36.11%**	20%
Which is the purpose of the surgery?	78.33%	0.56%	**11.67%**	6.67%	2.78%
What has caused the cataract?	**43.33%**	0%	10%	1.67%	45%
Is there an alternative to surgery that is definitive?	2.22%	1.11%	8.33%	18.33%	**70%**
Which of the following possible can happen if you do not operate?	61.67%	0.56%	0%	23.89%	**13.89%**
Which of the following statements about cataract surgery is false?	8.89%	17.22%	**22.78%**	28.33%	22.78%
Which of the following complications is less likely related to cataract surgery?	24.44%	15.56%	41.67%	**2.22%**	16.11%
Which of the following complications is less likely related to the anesthesia of cataract surgery?	15%	33.89%	11.11%	11.11%	**28.89%**
What is true about the indications and postoperative care of cataract surgery?	1.11%	7.22%	29.44%	**22.22%**	40%

Table 3- Ordinary regression model

	Estimate	Standard Error	Odds Ratio	95% Confidence Interval	P-value
Age (years)	-0.083	0.019	0.92	0.886 - 0.954	<0.001
Sex (women)	0.241	0.288	1.272	0.723 - 2.243	0.404
Secondary studies	1.845	0.362	6.331	3.147 - 13.058	<0.001
Tertiary studies	4.289	0.611	72.868	22.91 - 254.055	<0.001
Additional non-ophthalmological information (yes)	-0.247	0.291	0.781	0.44 - 1.381	0.397
Previous surgery (yes)	-0.211	0.372	0.81	0.389 - 1.681	0.571
Not accompanied in informed consent	0.295	0.347	1.343	0.68 - 2.656	0.396
Time (days) since signature informed consent	-0.003	0.004	0.997	0.989 - 1.006	0.535