

Baseline Cataract Status and 11-year Mortality: A Population-Based Study from a Mediterranean Population

Maria Pastor-Valero^{1,2*}, Juan Jose Miralles-Bueno¹ and Vicente Chaqués-Alepuz^{3,4}

¹Department of Public Health, History of Science and Gynaecology, Faculty of Medicine, (Muhammad Al- Shafra Building), Miguel Hernández University, Spain

²CIBER en Epidemiología y Salud Pública (CIBERESP), Madrid, Spain

³Head of Ophthalmology Department, Arnau de Vilanova Hospital, Valencia, Spain

⁴Department of Ophthalmology, Valencia University, Spain

*Corresponding author: Dr. María Pastor-Valero, Department of Public Health, History of Science and Gynaecology, Faculty of Medicine, (Muhammad Al- Shafra Building), Miguel Hernández University, Spain, Tel: (+34) 96 591 9506; Fax: 96 591 9551; E-mail: mpastor@umh.es, miralles_juabue@gva.es

Received date: Nov 26, 2014, Accepted date: Feb 26, 2015, Published date: Feb 28, 2015

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Abstract

Purpose: To examine the relationship between cataract, previous cataract surgery and risk of mortality in an elderly Mediterranean population.

Methods: This is a survival analysis of data from the Spanish centre of the European Eye Study (EUREYE) to examine 11-year-mortality risk among participants with previous cataract surgery or cataract compared to non-cataract participants diagnosed at the start of the study.

Results: After adjustment for age-related maculopathy (ARM), age, smoking, physical activity, obesity, diabetes mellitus, hypertension, previous stroke and heart attack, only the cataract no surgery group in men showed a significant elevated increased risk of mortality. The adjusted Hazard Ratio (HR) for the cataract no surgery men was, 1.96 95% CI (1.11-3.47) $p=0.020$ compared to non-cataract men.

Conclusion: We observed an increased risk of mortality in men with cataract in this elderly population. These results might indicate a differential use of medical services by elderly men compared to women. In addition, the lack of an increased mortality risk among the cataract surgery groups might be explained by the improvement in visual function. Future studies should include information on medical care use as well as information on measurements of pre and post-operative visual acuity.

Keywords Cataract; Mortality; Mediterranean population; Survival analysis

Introduction

The mechanism by which cataract might cause increased mortality is unknown but various hypotheses have been put forward. Studies have suggested that age-related cataract may be a marker of premature aging reflecting systemic diseases and early mortality [1]. Excess mortality has also been associated with poor vision, which could increase accident rates, loss of independence, and decreased social interaction leading to depression and higher cardiovascular mortality [2]. Cataract surgical complications have also been pointed out as one cause of excess mortality [1,3-7], but progress in phacoemulsification techniques have improved surgical safety and efficiency [2]. Moreover, studies have suggested that deaths due to cataract surgical complications are low, even for patients at higher preoperative risk [1,8].

Cataract, defined by the occurrence of past cataract surgery or as prevalent cases of cataract, has generally been shown to be associated with increased mortality either in the total study population [9] or in subpopulations defined by diabetic status [10-12]. However, none of these studies adjusted for the possible confounding effect of smoking. When other studies did, results continue to suggest an association

between either some types of cataract [13-16] or with cataract (cataract cases or past cataract surgery) and mortality [17].

However, some large population-based studies have not found any association between mortality and cataract. Results from the 12-year follow-up US male Physicians' Health cohort study indicated no association between reported history of cataract and increased mortality [18]. In this study, the general good health of the study population was mentioned as a limitation to the detection of an association. In fact, men with a previous history of myocardial infarction, stroke, cancer etc. were not eligible for inclusion. In two other large prospective population based studies, the Rotterdam cohort study [19] and the Beaver Dam Eye Study [20], and in the Medical Research Council (MRC) trial of assessment and management of older people in the community [21], an association was observed between cataract and mortality when adjusted by age and gender, but disappeared after correcting for all additional confounders. In a recent Chinese prospective population based study no type of cataract was associated with higher mortality [22].

With increasing survival of older people worldwide, cataract incidence and surgery will also increase. If cataract is established as a predictor of general frailty and early mortality then a comprehensive understanding of the role of cataract as a potential marker within the ageing process would help to design preventive policies for active

ageing and give information about the cost-effectiveness of cataract treatments.

To our knowledge this is the first study to examine the association between cataract status and mortality risk in an elderly Spanish population. The purpose of this research was to examine the relationship between cataract, previous cataract surgery and persons without cataract and risk of mortality in an elderly Mediterranean population.

Material and Methods

Study population and sample

This is a survival analysis of the Spanish centre of the European Eye Study (EUREYE) to examine 11-year-mortality risk among participants with previous cataract surgery or cataract compared to non-cataract participants diagnosed at the start of the study, between February 2000 and November 2001.

The EUREYE is a European multicentre population-based cross-sectional study aimed at estimating the prevalence of AMD (Age-related Macular Degeneration) and associated factors. A detailed description of the EUREYE study design and sampling was published previously [23,24]. Briefly, participants in the present study were recruited from random sampling of the population aged over 65, registered at that time in the National Office for Statistics Census as residents in Alicante province, Spain. The participation rate in the EUREYE study as a whole was 45%, with women and older age groups' participation rate being lower. In the Spanish centre the response rate was similar, with the participation rate of women aged 65-74 being 44.3%, ≥ 75 years being 39.2%, and for men aged 65-74 being 52.4%, and ≥ 75 years being 52.7%. Thus, of the 1000 eligible individuals for each centre, 600 agreed to participate at the Spanish centre. Although cataract was not an objective of the European study, there was local interest in examining the prevalence of cataract and associated factors [25]; hence, information relating to the presence of cataract or cataract surgery or its absence was collected from the Spanish participants.

Deaths occurring in the study cohort were traced by death certificates from the Spanish National Information System "Índice Nacional de Defunciones" (INDEF) [26] from date of enrolment 28/02/2001 up to 31/03/2012 (censored date). Ethical approval for the study was given by the Local Ethical Committee of Sant Joan University Hospital and Miguel Hernández University, Alicante, Spain. Written informed consent was obtained from all subjects.

Data collection and analysis

On the same day, and prior to the ophthalmic examination, participants were interviewed by trained fieldworkers in the hospital setting, using structure questionnaires for socio-demographic aspects (age, sex); lifestyle variables such as reported physical activity: sedentary, less active, active, smoking: never, past, current), medical conditions including reported history of diabetes, hypertension, previous stroke and heart attack. To assess nutritional status Body Mass Index (BMI) was used. The BMI was classified according to the WHO cut-off points for adult population and then re-categorized into obese BMI ≥ 30 kg/m² or non-obese BMI <30 kg/m² [27].

Ophthalmic examination

The ophthalmic examination was performed by one experienced ophthalmologist using slit-lamp bio microscopy. Cataract status was defined as any lens opacity in either eye or evidence of its removal (cataract surgery). A non-cataract case was any participant with no evidence of any lens opacities or previous surgery in either eye. Pupillary dilation was achieved using 1% tropicamide and/or 10% phenylephrine hydrochloride. Age-Related Maculopathy (ARM) was diagnosed using digital photography and the definitions of ARM based on the International Classification System for ARM. The signs of ARM were stratified using the Rotterdam staging system into 5 exclusive states (ARM-0-4) from 0 absence of any grades to grade 4: neovascular age-related macular degeneration [24].

Statistical methods

The aim of the present analysis was to examine the relationship between cataract prevalence, cataract surgery and non-cataract and 11 year mortality risk in an elderly Spanish Mediterranean population.

Descriptive statistics were generated for baseline characteristics of the participants and comparison was carried out between subjects with no cataract or with cataract diagnosed in either eye, or who had had cataract surgery in either eye by the start of the study (Table 1). Categorical variables are presented as numbers with percentages. The Pearson chi-square test was used to compare categorical data. For descriptive purposes, the characteristics of participants according to cataract status: no cataract, cataract no surgery and cataract surgery, were expressed as number and percentages. We performed bivariate analyses to determine the association between age-related characteristics and cataract status. The Pearson chi-squared test was used to compare proportions of categorical variables and medians of continuous variables (Table 1).

		No Cataract	Cataract No Surgery	Cataract Surgery	
		n (%)	n (%)	n (%)	P-value ¹
Sex	Women	87 (27.2%)	174 (54.4%)	59 (18.4%)	=0.813
	Men	72 (26.7%)	153 (56.7%)	45 (16.7%)	
Age	65-69	81 (45.5%)	84 (47.2%)	13 (7.3%)	<0.001
	70-74	48 (26.2%)	108 (59.0%)	27 (14.8%)	
	75-79	24 (19.4%)	74 (59.7%)	26 (21.0%)	

	80-100	6 (5.7%)	61 (58.1%)	38 (36.2%)	
ARM	Yes	76 (25.9%)	178 (60.8%)	39 (13.3%)	=0.008
	No	81 (29.8%)	133 (48.9%)	58 (21.3%)	
	Missing value	2	16	7	
Smoking	Never	99 (28.0%)	193 (54.5%)	62 (17.5%)	=0.896
	Past	39 (26.0%)	87 (58.0%)	24 (16.0%)	
	Current	21 (25.0%)	46 (54.8%)	17 (20.2%)	
	Missing value	0	1	1	
Physical activity	Sedentary	16 (15.8%)	60 (59.4%)	25 (24.8%)	=0.009
	A little active	106 (27.2%)	217 (55.8%)	66 (17.0%)	
	Active	37 (37.0%)	50 (50.0%)	13 (13.0%)	
Obesity	No	105 (28.0%)	202 (53.9%)	68 (18.1%)	=0.600
	Yes	54 (25.1%)	125 (58.1%)	36 (16.7%)	
Diabetes	Yes	28 (25.0%)	60 (53.6%)	24 (21.4%)	=0.514
	No	129 (27.2%)	266 (56.0%)	80 (16.8%)	
	Missing value	2	1	0	
Hypertension	Yes	64 (24.7%)	150 (57.9%)	45 (17.4%)	=0.150
	No	94 (28.9%)	173 (53.2%)	58 (17.8%)	
	Missing value	1	4	1	
Previous Stroke	Yes	6 (16.2%)	21 (56.8%)	10 (27.0%)	=0.125
	No	152 (27.8%)	303 (55.4%)	92 (16.8%)	
	Missing value	1	3	2	
Previous Heart attack	Yes	10 (26.3%)	23 (60.5%)	5 (13.2%)	=0.713
	No	149 (27.2%)	300 (54.8%)	98 (17.9%)	
	Missing value	0	4	1	
¹ Pearson chi-square test					

Table 1: Baseline characteristics among cataract surgery, cataract no surgery and no cataract subjects.

For all subjects, person-years of follow-up were calculated from the date of enrolment in the study until the earlier of date of death or March 31, 2012, end of the study, where those patients still living were censored. The Kaplan–Meier method and Log rank test were used to determine the survival rate and to compare the survival curves between the three groups, no cataract, cataract no surgery and cataract surgery participants (Figure 1). Age standardised mortality rates were calculated for each of the three groups of patients by dividing the number of deaths by person-time of follow up using the age structure of the whole cohort as the standard (Table 2).

The Cox proportional hazards regression analysis was used to estimate the association between cataract status at baseline and 11

years mortality. Wald test p values and 95% CI were calculated with the no cataract group used as the reference group (Table 3). Thus, three sets of models were presented in Table 3: model I, shows hazard ratios of mortality adjusted only by age and sex among the, cataract no surgery, and cataract surgery participants whereas model II and model III hazard ratios with further adjustments. We used Likelihood Ratio Test (LRT) for exclusion or inclusion of covariates using a backward procedure. All covariates with p values <0.05 or those reported in the biomedical literature as determinants of mortality were retained in the final models. Covariates which changed original estimated.

		Number	Died (%)	Person-years follow up	Mortality rate per 1000 person-years (95% CI) [*]
Women	No Cataract	87	20 (23.0)	809.3	24.7 (13.9-35.5)
	Cataract No Surgery	183	38 (20.8)	1646.9	23.1 (15.7-30.4)
	Cataract Surgery	51	17 (33.3)	515.5	33.0 (17.3-48.7)
Men	No Cataract	72	21 (29.2)	645.1	32.6 (18.6-46.5)
	Cataract No Surgery	153	68 (44.4)	1237.8	54.9 (41.9-68.0)
	Cataract Surgery	44	22 (50.0)	377.7	58.2 (33.9-82.6)

^{*}Age standardised

Table 2: Mortality rate and 95% confidence interval among cataract surgery, cataract no surgery and no cataract by sex.

		Adj. Hazard Ratio ² (95% CI)	p-value	Adj. Hazard Ratio ³ (95% CI)	p-value	Adj. Hazard Ratio ⁴ (95% CI)	p-value
Women	No Cataract	1.00		1.00		1.00	
	Cataract No Surgery	0.98 (0.51-1.85)	0.937	0.97 (0.51-1.85)	0.936	0.97 (0.49-1.90)	0.924
	Cataract Surgery	1.39 (0.67-2.89)	0.376	1.33 (0.63-2.81)	0.458	1.29 (0.58-2.86)	0.537
Men	No Cataract	1.00		1.00		1.00	
	Cataract No Surgery	1.86 (1.08-3.20)	0.025	1.92 (1.11-3.31)	0.019	1.96 (1.11-3.47)	0.020
	Cataract Surgery	1.71 (0.89-3.30)	0.108	1.63 (0.83-3.18)	0.155	1.64 (0.79-3.43)	0.184

¹Hazard ratios and 95% Confidence Interval (CI) were calculated using Cox proportional hazard regression analysis.
²Model 2: age-adjusted Hazard ratio for cataract status and mortality.
³Model 3: age-and ARM-adjusted Hazard ratio for cataract status and mortality.
⁴Model 4: Hazard ratio adjusted for age, smoking, physical activity, obesity, diabetes mellitus, hypertension, previous stroke and heart attack. P-value were calculated from Wald test.

Table 3: Mortality Hazard Ratios among cataract surgery, cataract no surgery and no cataract by gender¹.

Odd Ratio (OR) coefficients for more than 20% were also included as confounders. Thus model II was adjusted by age-sex and ARM and final model III also included smoking, physical activity, obesity, diabetes mellitus, hypertension, previous stroke, and heart attack. The proportional hazard assumptions were checked by plotting the Log Minus Log (LML) of the survival functions. If the hazards are proportional, the curves of the LML should be parallel. All co-variates included in the different Cox regression models fulfilled the proportional hazards assumptions. Statistical analyses were carried out by using the statistical packages for Stata software package v10 (StataCorp 2007 Stata Statistical Software: Release 10; StataCorp LP, College Station, TX) [28].

Results

The distribution of baseline characteristics of the population according to cataract status is shown in Table 1. Of the 599 elderly people recruited, a total of 590 subjects were included in the analyses, 26.9% (n=159) had no cataract, 73% (n=327) had cataract, and 17.6% (n=104) had had cataract surgery at the time of inclusion in the study. Of these, 26.9% (n=28) had had cataract surgery in one eye and 73.0% (n=76) in both eyes. There were no statistical differences in the prevalence of cataract or cataract surgery between women and men

(p=0.813). Women participants with cataract surgery were significantly older, mean age 77.75 (SD 7.39) years old followed by women with cataract, mean age 74.11 (SD 5.85) years old compared with women with no cataract, mean age 70.67 (SD 4.90) years old (p-value <0.001 and <0.001, respectively). Men with cataract surgery were also significantly older, mean age 75.36 (SD 7.10) years old compared to men with no cataract, mean 70.86 (SD 5.15) years old (p-value <0.001). However, no significant age differences were found between men with cataract, mean age 73.84 (SD 5.57) years old compared to men with no cataract (p-value=0.286).

The highest ARM (any grade >0) prevalence (60.8%) was observed in the cataract group, followed by the no cataract group (25.9%) and the cataract surgery group 13.3% (p=0.008). Participants with cataract (59.4%) or cataract surgery (24.8%) were significantly more sedentary than those without cataract (15.8%) p=0.009.

The Kaplan-Meier survival distribution function for the three groups, no cataract, cataract no surgery and cataract surgery is presented in Figure 1. First, we compared Kaplan-Meier survival curves between the three groups for both men and women. There was a significant decreased survival rate for the cataract surgery group followed by the cataract no surgery and then by the no cataract group (p=0.0001, log rank test). When we stratified by sex, women and men

with cataract no surgery and cataract surgery have increased mortality compared to women and men without cataract ($p=0.001$; $p=0.004$, log rank test, respectively) but in men the slope for the survival curves for both the cataract surgery and the cataract no surgery group was steeper than for women. ($p=0.009$; $p=0.744$, log rank test, respectively).

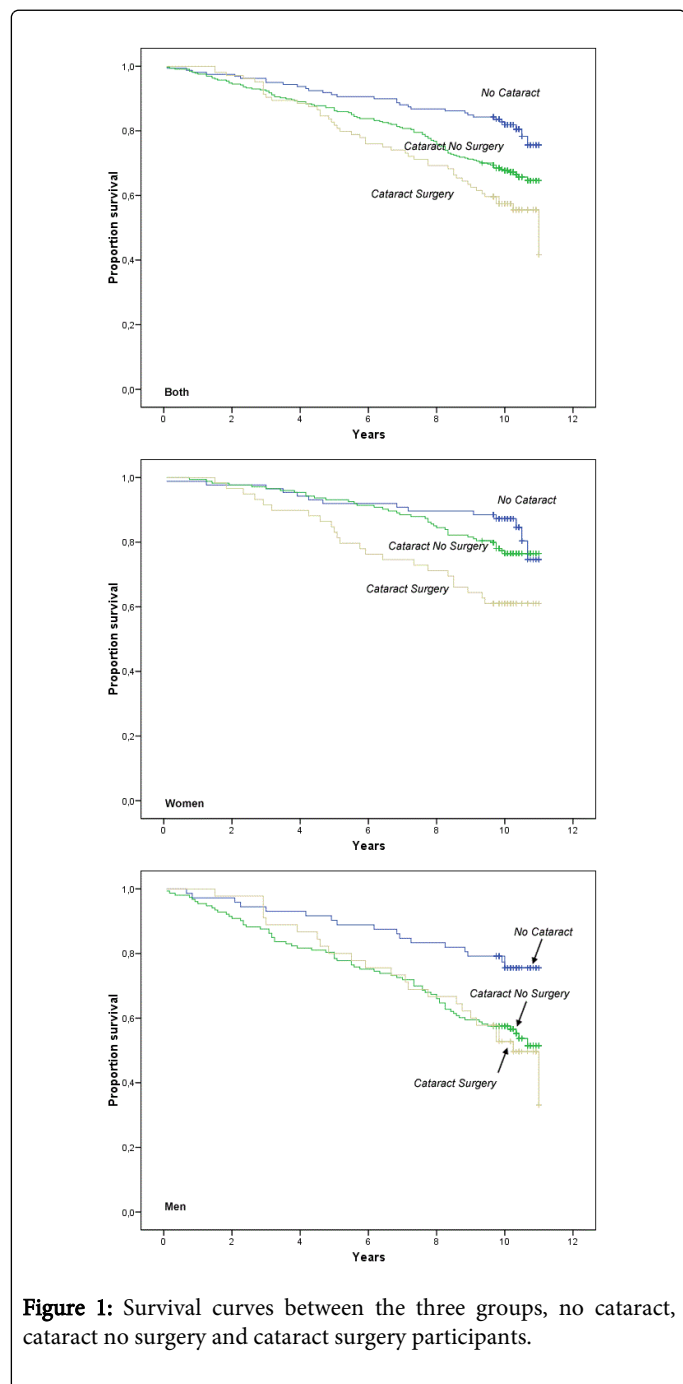


Figure 1: Survival curves between the three groups, no cataract, cataract no surgery and cataract surgery participants.

Table 2 presents the vital status of the participants. Between 28/02/2001 and 31/03/2012 there were 186 deaths (31.5%), 23.4% women ($n=75$) and 41.1% men ($n=111$). Median follow up was 10 years (range, 1-11 years). For both women and men, the age-adjusted mortality rate per 1000 person-years of those followed up was highest in the cataract surgery group followed by the cataract no surgery compared to the non-cataract group, although mortality rates were

almost double in men than in women for cataract surgery (58.2; 33.0, respectively) and cataract no surgery (54.9; 23.1, respectively).

Table 3 shows Hazard Ratios (HR) for mortality and 95% CI from Cox regression analyses by sex. Overall, men with cataract no surgery was more likely to die during the follow up than men with no cataract. Age-adjusted hazard ratios for men with cataract no surgery was 1.86 95% CI (1.08-3.20) $p=0.025$ and for cataract surgery was 1.71 (0.89-3.30) $p=0.108$ compared to the no cataract group. After adjustment for ARM, age, smoking, physical activity, obesity, diabetes mellitus, hypertension, stroke and heart attack, only the cataract no surgery group in men had a significant elevated increased risk of mortality. The adjusted HR for the cataract no surgery men was almost double that in men without cataract, 1.96 95% CI (1.11-3.47) $p=0.020$. The corresponding hazard ratios in women showed no association with mortality.

Discussion

After 11 years of follow-up the results of this study indicate that men with cataract compared to men without cataract had a significant increased risk of mortality, whereas men with previous cataract surgery compared to men without cataract showed a lower non-significant risk. In women, however, no increased risk of mortality was found for any cataract status (prevalence of cataract or cataract surgery) when compared to women without cataract.

In this study, the results for the men group are in line with several other studies, although they did not present their results separately for women and men. Thus, in the Blue Mountains Eye population-based study [29], increased 5-year-risk of mortality was found among those with any type of cataract, but no significant relationship was observed between past cataract surgery and risk of mortality when compared with persons without visual impairment. Similarly, the study by McGwin et al. [30], found a 4-year-increased mortality risk in patients with cataract who declined cataract surgery, but a lower and non-significant risk for those who opted for surgery compared with those without cataract but with other ocular diseases. In this study, it is likely that healthier patients systematically chose to have surgery performed, whereas those with more chronic ill health were not eligible. Blundell et al., [31] conducted a retrospective cohort study to re-evaluate mortality data in relation to cataract surgery, compared to national and regional mortality figures from England and Wales. They collected consecutive patients at the Bristol Eye Hospital during three months. They found no increased mortality following cataract surgery; in fact, they found significant reduced mortality for patients between 80 and 89 years of age when compared with the general population. Although they could not adjust by comorbidities due to the retrospective nature of the study, the authors made a valid point to sustain their results. Safety and efficiency in cataract surgery have improved with the introduction of the phacoemulsification techniques in the last two decades. In many countries, these changes have led to a greater number of patients being operated over a greater age range and with better preoperative vision, making the surgical population more representative of the general population, including the patterns of survival [31].

Previous cataract surgery cohort studies which found decreased survival did not use phacoemulsification technique for cataract removal [1,3-7,9]. The phacoemulsification technique was first introduced in the public hospitals in Alicante province in 1986, and although no direct information (medical records) on type of surgery

was collected in our study, we could infer this information since participants were asked about the year in which cataract surgery was performed. Thus, on average, men had had cataract surgery 8 years (\pm 6.6) before their entry in the study, and women, 6.2 years (\pm 4.8) before, so, we considered it highly likely that most, if not all, of our surgical cases had undergone cataract removal using the phacoemulsification technique.

It has been said that if cataract is a marker of cumulative oxidative damage in the body, and a marker of early mortality in the elderly, cataract removal might have no impact on mortality risk [30]. However, recent studies have shown that correcting moderate-severe visual impairment with phacoemulsification surgery was associated with a lower mortality risk, compared to cataract surgical patients whose visual impairment persisted postoperatively [31].

In the present study, the lack of a significant association between risk of mortality and the cataract surgery group might be related to the improvement in visual function following surgery and the subsequent decrease in falls, as well as improvement in daily activities and emotional well-being, i.e., the presence of cataract may reflect systemic decline which could be counteracted by improving the functional status thanks to cataract removal [30]. However, we could not examine this aspect since pre and postoperative visual impairment was not collected.

When interpreting the results of the present work, several possible limitations should be considered. HRs for mortality in men with previous cataract surgery were moderately high and borderline significant, and this might reflect a lack of statistical power. Cataract was assessed clinically during slit lamp examination by one ophthalmologist, without standard photos which are used in the cataract grading systems. It is, therefore, likely that if there was misclassification of cataract diagnosis this would most likely have occurred in early lens opacities. However, the literature does not suggest that there is an association of mortality with early lens opacities. Studies have shown poorer survival with severe nuclear or mixed cataracts, while the magnitude of the association was weaker or non-existent with early lens opacities. In addition, this study had a long follow-up, 11 years, but did not include follow-up visits, and therefore did not examine time-dependent variables. Thus, the information on baseline confounders may not reflect changes in these factors during the follow-up, and so may lead to misclassification of confounders. Even though we adjusted models for several known risk factors associated with both mortality and cataract at baseline, including ARM/AMD smoking, physical activity, obesity, diabetes mellitus, hypertension, previous stroke and heart attack, there is a likelihood that some important confounding factors may not have been controlled for, and we cannot, therefore, completely exclude the possibility of chance findings. For instance, we could not have anticipated the differential mortality risk by sex and we cannot offer any biological explanation for these results. We do not have information about health service use by this population associates to factors such as social network, socioeconomic status and cognitive deficit among others, and therefore the association seen in our study between cataract and mortality might reflect confounding by these factors, i.e., in this elderly population, cataract in men might be an indicator of poorer health associated with minimal use of medical services, including ophthalmological services, and/or inadequate control of other concomitant conditions in contrast to women. Elderly women in Spain have been shown to have a greater utilization of health-care services and lower hospitalization and this has been

associated to the number of chronic diseases and to Health-Related Quality of Life (HRQL) [32,33]. To our knowledge, the North London Eye Study is the only one which found a sex difference in increased mortality attributable to cataract, but in contrast to our results, they found an increased mortality risk for women, but not for men [34].

The participation rate was 50% and varied by age and sex [24]. The effect of the low response rate on our results is uncertain. Comparison between participants and non-participants in the present study was not possible because the mode of contact in the EUREYE study was restricted by ethical committees. People who refused to participate could not be re-contacted, and, therefore, information on cataract status or any other information, including the reasons for refusal, could not be collected [23]. Thus, if the decision not to participate was related to being older and in poorer general health, mortality risk would be underestimated and would bias the estimates in this study downward. The low response should also affect the external validity of our study, but generalizing the results to the whole population of elderly people in the Valencia region was beyond the scope of these analyses. The strengths of the study include its population-based sample, a long term follow-up, and ascertainment of mortality status using the Spanish National Death registry. In fact, we were able to confirm the death of 98% of participants who died during the follow up period using the Spanish National Information System "Índice Nacional de Defunciones" (INDEF) [26].

Conclusion

The increased risk of mortality in men with cataract could indicate a differential use of medical services by men with cataract compared to women. Future studies should include information on social determinants of health care use (such as socioeconomic level, isolation, education levels) by the elderly. We did not find an association between cataract surgery and mortality which might be due to the improvement in visual function. Future studies should also include measurements of pre and post-operative visual acuity.

Acknowledgments

I would like to acknowledge Laura Asensio (nurse research), who conducted data collection and the ophthalmologists from Sant Joan University Hospital, Alicante, who diagnosed the cataract. This study was supported by the Fondo de Investigaciones Sanitarias, Instituto de Salud Carlos III (Plan Nacional de I+D+I) PS 09/01627 and co-funded by the Fondo Europeo de Desarrollo Regional (FEDER).

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