Risk factors for posterior capsule rupture in cataract surgery as reflected in the European Registry of Quality Outcomes for Cataract and Refractive Surgery

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ABSTRACT

PURPOSE: To analyze the incidence and risk factors of posterior capsule rupture (PCR) in cataract surgery.

SETTING: European clinics affiliated with the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO).

DESIGN: Retrospective cross-sectional register-based study.

METHODS: Data was obtained from the EUREQUO. The database contains data on demographics, comorbidities, and intraoperative complications, including PCR for the study period from January 1, 2008, to December 31, 2018. Univariable and multivariable logistic regression analyses were performed to estimate the (adjusted) odds ratio (OR) and 95% confidence intervals (CI).

RESULTS: Data was available of 2,853,376 patients and 31,749 (1.1%) cataract surgeries were complicated by a PCR. The PCR rate ranged from 0.60 to 1.65 percent throughout the years, with a decreasing trend ($p < 0.001$). The mean age of the PCR cohort was 74.8 ± 10.5 years and 17,629 (55.5%) patients were female. Risk factors most significantly associated with PCR were corneal opacities (OR 3.21, 95% CI 3.02 – 3.41, $p < 0.001$), diabetic retinopathy (OR 2.74, 95% CI 2.59 – 2.90, $p < 0.001$), poor preoperative visual acuity (OR 1.98, 95% CI 1.88 – 2.07, $p < 0.001$), and white cataract (OR 1.87, 95% CI 1.72 – 2.03, $p < 0.001$).

CONCLUSION: Risk factors for PCR were identified based on the EUREQUO and the incidence of this complication is decreasing over time.

INTRODUCTION

Cataract surgery is the most commonly performed surgery in Europe. Each year about 4.7 million cataract surgeries are performed.[1] Although the risk of complications during cataract surgery is relatively low, damage to the posterior capsule is one of the most common and potentially sight-threatening complications.[2,3] A posterior capsule rupture (PCR) can lead to additional postoperative complications and surgical procedures.[4-7] Several risk factors have been identified, such as pseudoexfoliation, previous intravitreal injections, and an inexperienced surgeon.[2,8-10] The European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) provides a unique opportunity to analyze risk factors in multinational data on almost three million cataract surgeries. Identifying risk factors for PCR is crucial to identify patients at risk and manage patient expectations. This study sets out to determine the incidence and risk factors for PCR based on the EUREQUO.

METHODS

Data was obtained from the EUREQUO. The EUREQUO was instituted in 2008 as a co-project between the European Union (EU) and the European Society of Cataract and Refractive Surgeons (ESCRS).[11] In total, surgeons in 22 countries report data on cataract and refractive surgery to the EUREQUO. The clinics commit to entering all consecutive cases in the registry. Coding guidelines describe how variables are defined and should be reported. For this study, we only use the data on cataract surgery. The study was performed according to the tenets of the Declaration of Helsinki.

The database contains data on demographics, comorbidities, and intraoperative complications, including posterior capsule complication. Demographics included in this study are age, gender, year of surgery, and left or right eye. The preoperative parameters include corrected distance visual acuity (CDVA) in decimal (for analyses transferred to logMAR), target refraction, and comorbidities, such as macular degeneration, glaucoma, diabetic retinopathy, and other eye diseases with a potential threat to visual acuity. The intraoperative parameters are mechanical dilation of the pupil (a surrogate parameter for small pupil), use of trypan blue (a surrogate parameter for white cataract), disturbed visibility of cataract and capsule during surgery due to corneal opacities, and other difficulties during the surgery, like the use of hooks in the rhexis border, use of capsule tension ring and similar devices. Posterior capsule rupture is defined as an intraoperative tear in the posterior capsule with or without zonular dialysis and vitreous loss.

Statistical analysis

Statistical analyses were performed using SPSS software for Windows (version 25, SPSS, Inc.). Continuous variables were presented by mean and standard deviation (SD), and categorical data were presented by frequency and percentage. To analyze the trend in PCR rate a logistic regression model was constructed with the percentage of PCR cases as dependent variable and

the year of surgery as independent variable. Univariate logistic regression analyses were performed to estimate the odds ratio (OR) and 95% confidence intervals (CI) for age, gender, visual acuity, target refraction, ocular comorbidities, and difficulties during surgery. A backward stepwise method was used to construct a multivariate logistic regression model, including all statistically significant risk factors of the univariate logistic regression. A p-value of less than 0.05 was considered statistically significant. Only complete cases were analyzed and the mechanism of missing data was explored. Variance inflation factors (VIF) were calculated to quantify the correlation between the predictors in the model.

RESULTS

Demographics

From January 1, 2008, to December 31, 2018, the database contains data on 2,853,376 cataract surgeries. The surgical technique was phacoemulsification in 2,767,439 (97.0%) surgeries, extracapsular cataract extraction in 15,244 (0.5%) surgeries, laser-assisted cataract surgery in 4,766 (0.2%) surgeries, and phacoemulsification combined with a filtering procedure in 4,749 (0.2%) surgeries. In 61,178 (2.1%) procedures, data on the type of surgery was missing. The mean age of patients was 73.9 ± 9.7 years, and 58.7 percent were female. A PCR complicated 31,749 (1.1%) of reported surgeries. Among these patients, 17,629 (55.5%) were female, and the mean age was 74.8 ± 10.5 years. Surgery was performed on the left eye of 14,401 (45.4%) patients, with no significant difference in the operated side (OR 1.01, 95% CI 0.98 – 1.03, p-value 0.49). Table 1 and figure 1 shows the annual rate of PCR as the percentage of the total number of reported cataract surgeries. The PCR rate ranged from 0.60 to 1.65 percent throughout the years, with a decreasing trend (p <0.001).

Risk factors

A multivariable logistic regression analysis, including the statistically significant risk factors of the univariable analysis, was performed to determine possible risk factors associated with PCR. In the univariable analysis, amblyopia, macular degeneration, and previous vitrectomy were not significantly associated with PCR at the 5% level and therefore not considered in the multivariate model. In total, 1,722,022 cases were included in this analysis. Regarding age, gender, comorbidities, and complications reported, the excluded cases did not substantially differ from the included cases. Hence, it can be safely assumed that the missing cases are missing at random. The VIF for all parameters was below 1.8, indicating no considerable multicollinearity between the risk factors. Table 2 shows that male gender, increasing age,

~~glaucoma, diabetic retinopathy, other eye diseases with a potential threat to visual acuity, poor preoperative visual acuity, preoperative target hypermetropia, small pupil, white cataract, corneal opacities, pseudoexfoliation, and other intraoperative difficulties are significantly associated with PCR.~~Table 2 shows the multivariable model for risk factors associated with PCR including the adjusted odds ratios.

DISCUSSION

In this study, we identified multiple risk factors associated with PCR. These include male gender, advanced patient age, poor preoperative visual acuity and associated eye diseases, preoperative target hypermetropia, and surgical difficulties. We demonstrated a decreasing trend in PCR rate from 1.44 percent in 2008 to 0.60 percent in 2018. This decreasing PCR rate could be the result of a trend towards more experienced, high-volume surgeons, which decreases the risk of complications.[10,13] Also, improvements in phacoemulsification equipment or techniques over the years and surgery on younger and healthier eyes could have contributed to the decreasing trend.[14]

Age is significantly associated with PCR in our study, with an adjusted OR of 1.007. Although the OR for PCR increases only by 0.007 each additional year of age, this would mean the odds of an 80-year-old having a PCR is about 20 percent higher than a 55-year-old. This is in line with studies in the United Kingdom where a PCR complicated 2.7 percent of cataract surgeries of patients over 90 years of age compared to 1.95 percent among all ages.[15,16] ~~This OR seems relatively low, but the OR increases with 0.007 each additional year of age. For example, the odds of a patient who is 90 years old having a PCR is 1.25 compared to a patient who is 55 years old. Previous studies in the United Kingdom and Malaysia also show an association between PCR and advanced age.[2,14,15] For example, in the United Kingdom, 2.7 percent of cataract surgeries of patients of 90 years of age or older were complicated by PCR compared to~~

~~1.95 percent among all ages.[15]~~ This increased risk of PCR among the elderly may be caused by increased lens density and thickness, with ~~inadvertent~~ a concomitant decrease in zonular stability and strength with time, a more shallow anterior chamber, and decreased posterior capsule thickness, making cataract surgery more difficult. Besides, comfortable positioning may be an issue, as older patients may not be able to lie flat because of back or neck problems and cooperation may be limited due to hearing problems.[17]

Our study demonstrated that patients with hypermetropic target refraction (+0.51 to +6.00) have an increased risk of PCR, while patients with moderate to high myopic target refraction (-6.00 to -1.51) have a decreased risk of PCR. There are many reasons why patients would choose a target refraction that is not emmetropia, for example, myopic patients choosing for postoperative myopia to continue reading without glasses. Day et al.[18] found that eyes with an axial length of less than 20.0 mm showed a marginal increase in PCR rate. The increased PCR rate in hypermetropic eyes may be explained by a more shallow anterior chamber and reduced workspace for the surgeon.[5,18] Previous studies report varying results regarding the association between myopic patients and PCR. The PCR rate in eyes with axial length above 26.0 mm in these studies varied between 2.4 and 5.7 percent.[18-20] However, these smaller studies did not report the results adjusted for comorbidities more common in myopic patients, such as advanced levels of cataract, glaucoma, and poor preoperative visual acuity. An explanation for the decreased risk of PCR in myopic patients in the current study could be more working space for the surgeon due to a deeper anterior chamber.

Other risk factors significantly associated with PCR in our study are the use of trypan blue, mechanical dilation of the pupil, corneal opacities, diabetic retinopathy, glaucoma, pseudoexfoliation, male gender, and poor preoperative visual acuity. The surgical difficulties ‘use of trypan blue’ and ‘mechanical dilation’ of the pupil are surrogate markers for the preoperative risk factors white cataract and a small pupil. Previous smaller studies also reported

a significant association between PCR and white cataract, small pupil, ~~and~~ pseudoexfoliation, and diabetic retinopathy.[2,3,21] It has been proposed that diabetic retinopathy may increase the risk of PCR due to a more rigid pupil, advanced cataract, or previous intravitreal injections.[2,21] Chancellor et al. described an incidence of PCR of 2.3% in patients with diabetic retinopathy compared to 1.6% in patients without diabetic retinopathy.[21]

In the literature, no anatomical differences are reported in lens capsule or zonular stability between males and females that could explain the increased risk of PCR. An explanation of the higher incidence of PCR in males could be related to a higher incidence of intraoperative floppy iris syndrome (IFIS) in males.[22-24] Vollman et al. reported cataract surgery complicated with PCR in 6.9% of patients with IFIS compared to 3.7% of patients without IFIS.[25] A more shallow anterior chamber, zonulopathy, and small pupils, associated with glaucoma could explain the increased risk of PCR in glaucoma patients in the multivariable model.[26,27]

A previous vitrectomy was not significantly associated with PCR in our analyses. Interestingly, previous studies of the EUREQUO found an increased risk of dropped nucleus in patients with a previous vitrectomy but not an increased risk on PCR.[28,29] Studies performed in the United Kingdom support these results.[30,31]

Identifying risk factors for PCR is crucial to select patients at risk of this complication and to inform and manage the expectations of patients and ophthalmologists. Planning according to the risk profile may increase safety. For example, an elderly male patient with poor preoperative visual acuity, white cataract, and small pupil can better be scheduled for operation by an experienced surgeon. Moreover, it can be ensured that the necessary equipment is ready to use in the operating room. In New Zeeland and the United Kingdom, studies were performed with risk stratification scoring systems to allocate low-risk patients to trainees safely.[32,33] The New

Zealand Risk Stratification scoring system decreased the PCR rate from 2.6 percent at baseline to 0.6 percent in the study period. The results of our study can be used in such systems.

A limitation of this study is that risk factor analyses are limited to the indicators that are reported in the EUREQUO. For example, an association between PCR and previous intravitreal injections for age-related macular degeneration or IFIS secondary to medication could be evaluated if these parameters are added to the registry. On the other hand, the number of indicators must be considered to limit the burden of reporting and ensure the data is reliable. Another limitation is that data in EUREQUO is self-reported by surgeons and participating units, which means there is always a risk of complications being underreported. Previous studies indicate that the correct reporting of complications can vary, with a mean sensitivity of 54.0% ± 32.7 in these studies.[34-37] Also, Lundström et al. report a sensitivity of 65.5% and a specificity of 99.8% in a validation study of the Swedish National Cataract Register.[38] Nonetheless ~~However~~, participating clinics are committed to reporting to the EUREQUO to support quality improvement, and the percentage of PCR in our study cohort (1.1%) is in range with the percentages of recent studies (0.6 to 3.2%).[2,13] Besides, individual data of each clinic is only visible for that clinic, and there are no sanctions imposed. The study's strength is the large number of cases across different countries, making the statistical analyses more robust and the results more generable.

In conclusion, our study identified many risk factors for PCR based on the EUREQUO and showed that the incidence of this complication is decreasing over time.

What was known

Posterior capsule rupture is a feared complication of cataract surgery. Several risk factors have been proposed and the incidence is reported to decrease with modern cataract surgery.

What this paper adds

We identified new important risk factors for posterior capsule rupture, such as increasing age, poor preoperative visual acuity, hypermetropic target refraction, corneal opacities, diabetic retinopathy, and glaucoma. This information is of value for stratifying patients.

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Table 1. Reported cataract extractions with posterior capsule rupture (PCR) as a complication parameter in EUREQUO from January 1, 2008 to December 31, 2018.

	Year										
Parameter	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Reported cataract extractions including PCR (n)	165,650	201,377	227,181	249,458	260,805	280,906	300,145	261,740	282,246	305,846	318,022
Reported PCR (n)	2,387	2,725	2,708	3,976	2,896	4,181	4,958	1,969	2,025	2,007	1,917
Frequency (%)	1.44	1.35	1.19	1.59	1.11	1.49*	1.65*	0.75	0.72	0.66	0.60

* Cases from the ESCRS FLACS study are included.[12]

Figure 1. Reported cataract extractions with posterior capsule rupture (PCR) in EUREQUO from January 1, 2008 to December 31, 2018.

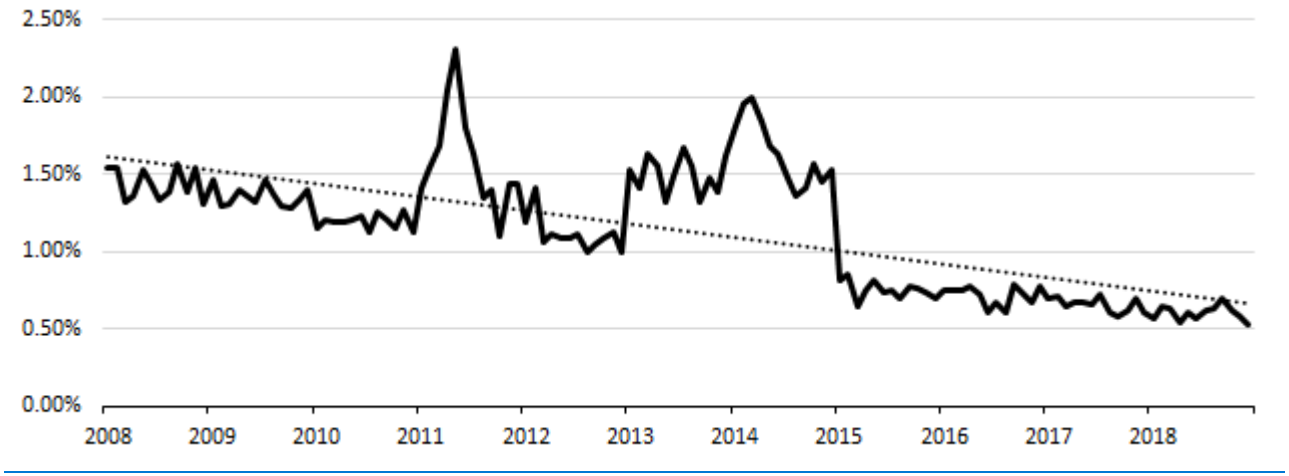

Table 2. Multivariable logistic regression model for risk factors associated with posterior capsule rupture in EUREQUO.

Parameter	Adjusted OR	95% CI		P-value
		Lower	Upper	
Year of surgery[a]				
2008	2.12	1.95	2.31	<0.001
…				
2017	0.99	0.90	1.08	0.801
2018	-	-	-	-
Gender (female)	0.88	0.85	0.90	<0.001
Age	1.007	1.005	1.008	<0.001
Glaucoma	1.16	1.09	1.23	<0.001
Diabetic retinopathy	2.74	2.59	2.90	<0.001
Other comorbidity	3.03	2.91	3.16	<0.001
Preoperative CDVA (logMAR)	1.98	1.88	2.07	<0.001
~~*Preoperative t*~~*Target refraction*[b]				
Myopia (-6.00 to -1.51)	0.74	0.69	0.79	<0.001
Mild myopia (-1.50 to -0.51)	0.97	0.92	1.03	0.366
Emmetropia (-0.50 to +0.50)	-	-	-	-
Mild hypermetropia (+0.51 to +1.50)	1.24	1.08	1.43	0.002
Hypermetropia (+1.51 to +6.00)	1.37	1.13	1.65	0.001
Small pupil	1.23	1.13	1.33	<0.001
White cataract	1.87	1.72	2.03	<0.001
Corneal opacities	3.21	3.02	3.41	<0.001
Pseudoexfoliation	1.37	1.18	1.60	<0.001
Other difficult surgery	1.36	1.30	1.43	<0.001

CDVA = corrected distance visual acuity, CI = confidence interval, logMAR = logarithm of the minimum angle of resolution, OR = odds ratio.

[a] ~~Odds ratios are compared to~~ Reference category: 2018

[b] ~~Odds ratios are compared to~~ Reference category: emmetropia