• Investigation •

Are there sex-based disparities in cataract surgery?

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Abstract

● **AIM:** To investigate sex-based differences in the occurrence of intra-operative and post-operative complications and associated visual outcomes following cataract surgery.

● **METHODS:** This was a retrospective study of patients who had phacoemulsification cataract surgery at the University of Colorado School of Medicine. Data collected included the patient's health history, ocular comorbidities, operative and post-operative complications, and the post-operative best corrected visual acuity (BCVA). The data were analyzed using univariate and multivariable logistic regression with generalized estimating equations to account for the correlation of some patients having two eyes included in the study.

● **RESULTS:** A total of 11 977 eyes from 7253 patients were included in the study. Ocular comorbidities differed by sex, with males having significantly higher percentages of traumatic cataracts (males 0.7% *vs* females 0.1%), prior ocular surgery (6.7% *vs* 5.5%), and mature cataracts (2.8% *vs* 1.9%). Conversely, females had significantly higher rates of pseudoexfoliation (2.0% *vs* 3.2%). In unadjusted analysis, males had higher rates of posterior capsular rupture (0.8% *vs* 0.4%) and vitreous loss (1.0% *vs* 0.6%), but this difference was not significant after adjustment for confounders. Males had a significantly increased risk of post-operative retinal detachment, but in multivariable analysis this was no longer significant. Males were significantly less likely to undergo post-operative neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy for posterior capsule opacification (OR=0.8, 95%CI=0.7-0.9, *P*=0.0005). The BCVA was slightly worse for males pre-operatively; but post-operatively, both sexes exhibited similar visual acuity of Snellen equivalent 20/25.

● **CONCLUSION:** The study finds that in a cohort of patients presenting for cataract surgery, sex differences exist in pre-operative comorbidities and surgical characteristics that contribute to higher rates of some complications for males. However, observed surgical complication rates exhibit almost no difference by sex after adjusting for pre-operative differences and post-operative BCVA is similar between sexes.

● **KEYWORDS:** cataract surgery; sex-based disparity; phacoemulsification; outcomes

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INTRODUCTION

Cataract is a leading cause of avoidable visual impairment worldwide. According to the 2020 Global Burden of Disease study, 15.2 million cases of blindness and 78.8 million cases of moderate to severe visual impairment are caused by cataracts worldwide[1]. The Centers for Medicare and Medicaid Services indicate that approximately 3.4 million cataract surgeries are performed each year costing nearly US$3.4 billion in the United States[2-5]. Fortunately, cataract surgery has a high success rate for restoring vision[3]. However, in some cases complications can occur either intra-operatively or post-operatively[2]. Complications and ocular comorbidities are the main factors that lead to poor visual outcomes following cataract surgery.

Sex-based disparities have received increasing attention since the National Institutes of Health issued its policy on the consideration of sex as a biological variable[6]. Yet, gender disparities have not yet been widely studied in the field of ophthalmology. A recently published article on the role of sex and gender in eye health stated that "Sex and gender should also be prioritized for guidance on research questions and outcomes data analyses"[7]. The integration of sex and gender differences into clinical research has been shown to inform the pathogenesis of disease[8-10], sex-specific risk factors[11], patient management, and treatment protocols[12].

In regards to cataract surgery, it is recognized that females are at a higher risk of developing cataracts than males[13-14], possibly due to post-menopausal declining levels of estrogen[13,15] and a longer life expectancy[10,16-17]. In developing countries, women with cataracts continue to disproportionately suffer from lack of access and worse visual outcomes post-operatively, specifically in places where cataract outcomes remain below the goal established in the World Health Assembly 2013 Global Action Plan goal[1,18]. However, the frequency and type of cataract surgery complications are understudied when considering sex differences related to patient comorbidities at time of presentation for cataract surgery[19]. Therefore, the purpose of this study was to determine if there are sex differences in regards to comorbidities at time of presentation, intra-operative complications, post-operative complications, and visual outcomes following cataract surgery.

SUBJECTS AND METHODS

Ethical Approval Due to the retrospective nature of the study, informed consent was not obtained from patients. This study was approved by the Colorado Multiple Institutional Review Board (COMIRB #17-0629) and is aligned with the tenants established in the Declaration of Helsinki.

The records of patients who underwent phacoemulsification cataract surgery (January 1, 2014 through September 30, 2019) at the Sue Anschutz-Rodgers Eye Center, University of Colorado School of Medicine were examined by a team of trained researchers. The data were entered into a secure cataract outcomes database, which has been described in detail in several other publications[20-22]. Patients less than 50 and greater than 99 years of age were excluded from the analytic dataset.

Patient demographics and clinical characteristics such as general health history and ocular comorbidities were collected from the medical chart. Variables specifically included for this study were patient ethnicity, age, history of autoimmune disease (rheumatoid arthritis, fibromyalgia, systemic lupus erythematosus, multiple sclerosis, Sjögren's syndrome, and Crohn's disease), heart disease, treatment for chronic hypertension, type 2 diabetes, and treatment with tamsulosin. Ocular comorbidities included traumatic cataract, pseudoexfoliation, prior intraocular injection, mature cataract, glaucoma, and age-related macular degeneration. Other information collected included the need for combined and complex surgery. Combined surgery included cataract surgery performed in combination with pars plana vitrectomy (PPV; captured as either planned or unplanned), glaucoma surgery [endoscopic cyclophotocoagulation, Kahook Dual Blade (New World Medical Inc, Rancho Cucamonga, CA, USA), iStent (Glaukos Corp, Laguna Hills, CA, USA), and tube shunts], or corneal transplant. Complex surgery included cases that required any iris manipulation (iris hooks, Malyugin ring, stretch pupilloplasty), anterior capsule stain due to poor visualization (trypan blue), capsular support device, and/or capsular hooks. Whether surgery was performed largely by a resident in training versus an attending was collected. The type of lens implanted was categorized as monofocal, monofocal toric, or multifocal/extended depth of focus.

All cataract surgeries utilized phacoemulsification and were performed or overseen by attending faculty cataract surgeons. The primary outcomes of the study were intra-operative complications, post-operative complications, and visual acuity. The intra-operative complications examined were posterior capsular rupture (PCR), vitreous loss, retained lens fragment, choroidal hemorrhage, and zonular dialysis. The post-operative complications documented within 1y of surgery included endophthalmitis, cystoid macular edema (CME), and retinal detachment. Neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy for posterior capsule opacification (PCO) was also a documented post-operative outcome if it occurred at any point following cataract surgery. Visual acuity was recorded for patient eyes both pre-operatively and post-operatively. Post-operative best corrected visual acuity (BCVA) in this study indicates the best vision attained through manifest refraction, glasses, or contacts. Post-operative BCVA was the best visual acuity measured within one year after cataract surgery and was converted to logMAR for statistical analysis.

Statistical Analysis Demographics, medical history, ocular comorbidities, surgical characteristics, complications, and pre-operative and post-operative visual outcomes were analyzed by sex. For intra-operative and post-operative complications, comparisons between sex were made amongst the entire cohort, as well as after excluding those surgeries performed in combination with planned PPV. Visual acuity summary measures are presented for the entire cohort and for a sub-cohort excluding data from cases of all combined surgeries with PPVs, traumatic cataracts, and intra-operative complications (PCR, vitreous loss, retained lens fragment, choroidal hemorrhage, and zonular dialysis).

Patient level comparisons by sex were analyzed with logistic regression with generalized estimating equations to account for correlation between eyes from the same subject. For the eye-level analyses of binary outcomes, logistic regression modeling with generalized estimating equations were used. For continuous visual outcomes, linear regression modeling was used with generalized estimating equations. For multivariable analyses, covariates for adjustment were chosen based on significant univariate associations with sex, the primary explanatory variable of interest, and each specific outcome. For the outcomes of choroidal hemorrhage and endophthalmitis,

adjustment was not possible due to one or more group size values of zero. For the outcome of PCR, a combined variable for rare and/or sex-specific risk factors that included traumatic cataract, mature cataract, history of ocular injection, prior ocular surgery, and treatment with tamsulosin was included in the multivariable model. A *P*-value < 0.05 was considered significant and all statistical analyses were performed using SAS software (version 9.4, SAS Institute Inc., Cary, NC, USA).

RESULTS

In Table 1, we display the demographic and clinical characteristics by sex of the 7253 patients included in the study. Females represented 4180 (57.6%) of the cohort. Race and ethnicity were similar by sex, with the exception of significantly more females who were Asian (5.1%) compared to males (3.1%; *P*=0.0002). The average age at the time of cataract surgery was similar by sex with a mean of 70.6y for males and 70.2y for females (*P*=0.0536). Males had a significantly higher percentage of the following medical comorbidities at the time of first cataract surgery: heart disease, treatment for chronic hypertension, type 2 diabetes, and treatment with tamsulosin (all *P*<0.0001). Females had a higher rate of autoimmune disease (*P*<0.0001).

Table 2 displays the ocular comorbidities and surgical characteristics from the 11 977 eyes that underwent cataract surgery. Males had significantly higher percentages of traumatic cataracts, prior ocular surgery, and mature cataracts. Conversely, females had a significantly higher percentage of pseudoexfoliation. Rates of previous intraocular injections, glaucoma, and age-related macular degeneration did not differ by sex. Males had significantly longer axial lengths than females [mean of 24.6 mm (SD: 1.4 mm) *vs* 24.0 mm (SD: 1.5 mm), *P*<0.0001]. Further, males were significantly more likely to undergo planned PPV (1.3% *vs* 0.9%, *P*=0.0296) and have complex surgery (19.0% *vs* 12.6%, *P*<0.0001) compared to females. The proportion of surgeries performed largely by residents were similar for males (6.6%) and females (6.0%) and missing for 35 cases. Monofocal lenses were implanted at similar rates, 89.7% for males and 88.0% for females. However, a higher percentage of females received multifocal lenses (5.6%) compared with males (3.8%; *P*=0.0015).

In Table 3 we display univariate and multivariable results of intra-operative complications. As shown by univariate analysis, in the entire cohort and in the cohort that excluded cases that underwent planned PPVs, the incidences of PCR and vitreous loss were higher for males (0.8% for PCR and 1.0% for vitreous loss) compared with females (0.4% and 0.6%, respectively). However, in the multivariable analysis of vitreous loss, which adjusted for mature cataract and complex surgery, male sex was no longer associated with increased incidence of vitreous loss. For the PCR outcome, we adjusted for complex surgery, diabetes and a combined risk factor variable that includes mature cataract, prior ocular surgery, history of ocular injection, and treatment with tamsulosin. After adjustment, male sex was no longer associated with PCR.

In Table 4, we display the results of our univariate and multivariable analysis of post-operative complications by sex. Rates of retinal detachment were significantly higher in males when evaluated within the entire cohort (0.7% versus 0.3%, *P*=0.0009) and after excluding planned PPVs (*P*=0.0043). However, in the multivariable analysis following adjustment for mature cataracts, complex surgery, PCR, and

Table 1 Demographic and clinical characteristics of the patient cohort by sex *n*=7253, *n* (%)

Parameters	Male	Female	*P*
Demographics	3073 (42.4)	4180 (57.6)	-
Race/ethnicity			
White/Caucasian	2291 (74.6)	3050 (73.0)	Reference
Hispanic	270 (8.8)	356 (8.5)	0.9098
Black/African American	260 (8.5)	357 (8.5)	0.7210
Asian	96 (3.1)	213 (5.1)	0.0002
Others/unknown	156 (5.1)	204 (4.9)	0.8703
Age (y), mean±SD	70.6±9.1	70.2±8.4	0.0536
Medical history			
Autoimmune disease	144 (4.7)	480 (11.5)	<0.0001
Heart disease	1054 (34.3)	912 (21.8)	<0.0001
Treatment for chronic hypertension	1896 (61.7)	2299 (55.0)	<0.0001
Type 2 diabetes	782 (25.4)	883 (21.1)	<0.0001
Treatment with tamsulosin	427 (13.9)	5 (0.1)	<0.0001

SD: Standard deviation; PPV: Pars plana vitrectomy.

Table 2 Ocular comorbidities and characteristics of cataract surgeries by sex *n*=11977, *n* (%)

Parameters	Male	Female	*P*
Eyes investigated	4941 (41.2)	7036 (58.8)	-
Ocular history			
Traumatic cataract	36 (0.7)	7 (0.1)	<0.0001
Pseudoexfoliation	97 (2.0)	223 (3.2)	0.0021
Intraocular injections	193 (3.9)	225 (3.2)	0.0660
Prior ocular surgery	333 (6.7)	389 (5.5)	0.0132
Mature cataract	137 (2.8)	134 (1.9)	0.0026
Glaucoma	758 (15.3)	1,039 (14.8)	0.5019
Age-related macular degeneration	470 (9.5)	628 (8.9)	0.4027
Axial length (mm), mean±SD	*n*=4783, 24.6±1.4	*n*=6844, 24.0±1.5	<0.0001
Characteristics of cataract surgeries			
Combined surgery			
Planned pars plana vitrectomy	63 (1.3)	62 (0.9)	0.0296
Any type of combined surgery	667 (13.5)	922 (13.1)	0.6134
Surgery performed by resident	323 (6.6)	424 (6.0)	0.3362
Complex surgery	940 (19.0)	885 (12.6)	<0.0001
Type of lens implanted			
Monofocal	4431 (89.7)	6188 (88.0)	Reference
Multifocal/extended depth of focus	187 (3.8)	397 (5.6)	0.0015
Monofocal toric	323 (6.5)	451 (6.4)	0.9986

SD: Standard deviation; PPV: Pars plana vitrectomy; PCR: Posterior capsular rupture.

Table 3 Univariate and multivariable analysis of intra-operative complications by sex *n* (%)

Parameters	Entire cohort			Excluding planned PPVs				
	Male	Female	*P*	Male	Female	*P*	Multivariable[a] odds ratio for males (95%CI)	*P*
PCR	40 (0.8)	30 (0.4)	0.0077	35 (0.7)	28 (0.4)	0.0215	1.3 (0.7-2.2)	0.4109
Vitreous loss	49 (1.0)	41 (0.6)	0.0124	47 (1.0)	38 (0.5)	0.0093	1.4 (0.9-2.2)	0.1100
Retained lens fragment	23 (0.5)	29 (0.4)	0.6620	23 (0.5)	29 (0.4)	0.6516	1.0 (0.6-1.6)	0.8712
Choroidal hemorrhage	2 (0.04)	2 (0.03)	0.7005	2 (0.04)	2 (0.03)	0.6971	-	-
Zonular dialysis	38 (0.8)	42 (0.6)	0.2625	36 (0.7)	41 (0.6)	0.3247	0.9 (0.6-1.4)	0.7137

-: Not calculated due to small numbers. [a]Outcomes of vitreous loss, retained lens fragment, and zonular dialysis adjusted for mature cataract and complex surgery. Outcome of PCR adjusted for complex surgery, diabetes, and a combined risk factor variable that includes mature cataract, traumatic cataract, prior ocular surgery, history of ocular injection, and treatment with tamsulosin. PPV: Pars plana vitrectomy; PCR: Posterior capsule rupture; CI: Confidence interval.

Table 4 Univariate and multivariable analysis of post-operative complications by sex *n* (%)

Parameters	Entire cohort			Excluding planned PPVs				
	Male	Female	*P*	Male	Female	*P*	Multivariable[b] odds Ratio for males (95%CI)	*P*
Endophthalmitis	4 (0.08)	3 (0.04)	0.4010	4 (0.08)	3 (0.04)	0.3981	-	
Retinal detachment	35 (0.7)	18 (0.3)	0.0009	30 (0.6)	17 (0.2)	0.0043	1.0 (1.0-1.0)	0.0663
Nd:YAG laser capsulotomy for PCO	514 (10.4)	936 (13.3)	<0.0001	502 (10.3)	922 (13.2)	<0.0001	0.8 (0.7-0.9)	0.0005
CME	126 (2.6)	139 (2.0)	0.0654	116 (2.4)	136 (2.0)	0.1627	1.1 (0.9-1.5)	0.3353

-: Not calculated due to small numbers. [b]Outcome of retinal detachment adjusted for mature cataract, complex surgery. PCR, and axial length. Outcome of CME adjusted for mature cataract and complex surgery. Outcome of Nd:YAG laser capsulotomy adjusted for traumatic cataract, mature cataract, complex surgery, type of lens, and pre-operative BCVA. PPV: Pars plana vitrectomy; PCR: Posterior capsular rupture; Nd:YAG: Neodymium-doped yttrium aluminum garnet; PCO: Posterior capsular opacification; CI: Confidence interval; CME: Cystoid macular edema.

Table 5 Pre-operative and post-operative visual acuity by sex

Parameters	Male (*n*)	Male, mean±SD, logMAR	Female (*n*)	Female, mean±SD, logMAR	*P*
BCVA before surgery					
Entire cohort	4941	0.389±0.53	7020	0.347±0.47	<0.0001
Sub-cohort[c]	4767	0.365±0.49	6874	0.333±0.44	0.0009
BCVA after surgery					
Entire cohort	4466	0.108±0.30	6404	0.099±0.28	0.1432
Sub-cohort[c]	4308	0.092±0.26	6264	0.090±0.26	0.6915

[c]Excluded all PPVs, traumatic cataracts, and intra-operative complications (PCR, vitreous loss, retained lens fragment, choroidal hemorrhage, and zonular dialysis measure). BCVA: Best corrected visual acuity; PPV: Pars plana vitrectomy; SD: Standard deviation; PCR: Posterior capsule rupture.

axial length, retinal detachment did not significantly differ. Nd:YAG laser capsulotomy for PCO was significantly higher in females (13.3%) than males (10.4%) across the entire cohort (P<0.0001) as well as following exclusion of patients who had a planned PPV (P<0.0001). In the multivariable analysis (after adjusting for traumatic cataract, mature cataract, complex surgery, and type of lens) Nd:YAG laser capsulotomy for PCO still exhibited a significantly lower rate in males compared to females (odds ratio=0.8, 95%CI=0.7-0.9, P=0.0005).

Table 5 presents the pre-operative and post-operative visual acuity by sex for the entire cohort and a sub-cohort that excludes combined cases with PPVs, traumatic cataracts, and cases with intraoperative complications. Females had better pre-operative BCVA than males in both the entire cohort and sub-cohort. In the sub-cohort, females had an average pre-operative BCVA of logMAR 0.347 (20/44 Snellen equivalent), which was better compared to the average for males of logMAR 0.365 (20/46 Snellen equivalent; P=0.0009). Post-operatively, the BCVA after surgery was not statistically different between males and females (approximately 20/25 Snellen equivalent) for the entire cohort (P=0.1432) and sub-cohort (P=0.6915).

DISCUSSION

This study demonstrates important sex differences and similarities for cataract surgery patients in regard to comorbidities at presentation, rates of complications, and visual outcomes. Moreover, despite some significant variation in risk factors and complications, patient sex does not significantly affect

the primary outcome of post-operative visual acuity. Notable findings of this study were that intra-operatively males had higher unadjusted rates of PCR and vitreous loss compared to females. Post-operatively, males also demonstrated a higher unadjusted rate of retinal detachment and females were more likely to undergo Nd:YAG laser capsulotomy for PCO. Pre-operative BCVA was significantly worse for males, yet even with different rates of comorbidities and complications, males and females exhibited similar post-operative BCVA of approximately 20/25 Snellen. The sex difference in Nd:YAG rates was the only outcome that remained significant after adjustment for confounding risk factors.

Known risk factors for PCR include prior ocular surgery, age, mature cataracts, history of doxazosin (alpha-1 adrenergic blocker) treatment, and diabetes[23-24]. Other authors have also identified that male sex was a risk factor for PCR when undergoing cataract surgery[23-26]. Our results support that males were at significantly higher risk of PCR in univariate models and this association persisted after excluding planned vitrectomies, however, after adjustment for other risk factors there was no significant difference by sex. Another finding of our study was a higher rate of vitreous loss for males than females in the univariate analysis. This is not surprising as PCR and vitreous loss are related intra-operative complications that frequently occur in tandem[3,23].

Our study found retinal detachments to be a post-operative complication occurring at a significantly higher rate in males compared to females prior to adjustment for confounding factors. However, in multivariable analysis the odds of retinal detachments were similar between males and females. As reported in other studies as risk factors for retinal detachment[27-29], we also found that males have higher prevalence of traumatic cataracts, prior ocular surgery, PCR, and longer axial lengths. In our study, adjustment for axial length primarily accounted for the sex disparity in retinal detachment. Sheu *et al*[27] examined sex differences for retinal detachment following cataract surgery and found that longer axial length and younger age were retinal detachment risk factors primarily for males, not females.

Another finding of this study was that males were twenty percent less likely than females to undergo Nd:YAG due to PCO. This post-operative complication was significant in both the univariate and multivariate analysis of our study. Ando *et al*[30] had similar findings to our study that indicate Nd:YAG laser for posterior capsulotomy occurred more frequently in females than males. One potential reason for this difference could be that females, in general, are more likely to seek healthcare sooner[17,31]. Another similar explanation could be that males accept a greater degree of visual loss than females, which was also indicated by males presenting for cataract surgery at a worse BCVA that females in our present study.

A primary objective of this study was to determine the role of sex differences on pre-operative and post-operative BCVA. We found that average female pre-operative BCVA was better than average male pre-operative BCVA (Snellen equivalent 20/44 for females and 20/46 for males). Although statistically significant, this difference is small and did not impact post-operative visual outcomes since males and females had similar BCVAs following surgery. Other studies have also found that females have better pre-operative visual acuity than males, which is likely a result of the aforementioned points of males being subjectively less concerned by decreased visual function[17,31] and that males are more likely to wait longer before seeking care[31]. On the contrary, in developing countries, female vision is markedly worse than males at time of cataract surgery, where education and access to vision care are often more challenging for females[3,32-34]. While our results demonstrate similar BCVA after surgery, Hughes *et al*[35] concluded statistically significant differences in BCVA outcome based on comorbidity and sex to elucidate the importance of considering comorbidity and sex as two contributing factors for IOL power formulas. Our statistical analysis in Table 5 demonstrates that when controlling for factors that produced changes to the BCVA in their study, we did not face the same vision changes due to variables like PPVs, traumatic cataracts, and intra-operative complications. Thus, it is imperative to note that the findings from our study may only be representative of cataract surgery in the United States.

The retrospective nature of this study presents limitations to our investigation given the reliance on the accuracy of patient chart information. However, given the large sample size in our study and the meticulous data abstraction by our research team, we have confidence in the integrity of the information collected in this cataract surgery database. A strength of our study is that in addition to our analysis that focused on sex differences in the entire cohort, we also included analyses of sub-cohorts and adjusted multivariable modeling to control for the most important confounding variables. We present both unadjusted and adjusted data since both are important in regard to patient care, as well as the reporting and understanding of sex disparities.

In conclusion, results of our study findings demonstrate important differences in comorbidities by sex, which lead to differences in rates of complications in cataract surgery with males having higher rates of PCR, vitreous loss, and retinal detachments in univariate analyses. Following adjustment in the multivariable model, these complication rates were no longer statistically significant. In addition, despite males generally presenting with more comorbidities, worse pre-operative BCVA, and higher rates of complications, the post-

operative mean BCVAs were similar by sex even in the unadjusted analysis. One finding that remained significant in both the univariate and multivariate model was higher rates of Nd:YAG laser for PCO in females during the post-operative period. Our study indicates that understanding sex-specific risk factors regarding cataract surgery may aid physician expectations and their knowledge to best counsel patients. It also provides reassurance that on average males and females can expect similar visual outcomes despite their differences in presentation and complications as seen in this university-based hospital in the United States.

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