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Serious Adverse Events After Cataract Surgery

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Abstract

Purpose—Over the past several decades there have been many advances in the equipment, instrumentation and techniques of performing cataract surgery. This review will address the impact of these advances on the safety profile of cataract surgery.

Recent Findings—Recent studies have demonstrated a decline in the risk of serious postoperative adverse events (endophthalmitis, suprachoroidal hemorrhage, retinal detachment) following cataract surgery. Factors that increase the risk of serious complications from cataract surgery include patient-related factors (male sex, concomitant diabetic retinopathy, same day cataract surgery combined with another intraocular surgery, tamsulosin use) and surgeon-related factors (low surgical volume, limited experience, operating on patients who are most prone to adverse events).

Summary—Cataract surgery continues to be a very safe surgical procedure with few patients experiencing serious sight-threatening adverse events. Studies in the literature have helped surgeons identify patients who are at high risk for surgical complications and to develop strategies to limit surgical complications when operating on these patients. As multifocal intraocular lenses, femtosecond laser technology, and other surgical innovations continue to gain popularity, it will be interesting in the coming years to determine whether there will be a continued reduction in complications of cataract surgery.

Keywords

Cataract surgery; adverse events; complications

Introduction

Surgeons continually look for techniques to improve the efficiency, safety profile, and outcomes of cataract surgery, the most common surgical procedure in the United States. This review highlights the impact of technological advances in cataract surgery on rates of serious adverse events. Recent studies identifying patient- and surgeon-related factors that affect the risk for serious intraoperative or postoperative complications are also reviewed.

Trends in Complication Rates by Type of Surgery

Several studies have compared rates of adverse events as surgeons transitioned from intracapsular cataract extraction (ICCE) to extracapsular cataract extraction (ECCE) surgery, and of the two procedures ECCE has generally had the better safety profile. In a study performed at Aravind Eye Hospital, one-year rates of serious postoperative complications were more common with ICCE surgery (14.5%) than with ECCE surgery (7.7%).^[1] In two

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other studies, endophthalmitis rates also were lower among patients undergoing ECCE than those having ICCE.[2,3]

Unlike with the transition from ICCE to ECCE, studies comparing postoperative complication rates with the transition from ECCE to phacoemulsification have found little difference between the two techniques. For example, Schein *et al.* reported similar rates of intraoperative and postoperative adverse events after ECCE and phacoemulsification.[4] Likewise, an analysis of 117,083 cataract surgeries performed in Australia during 1980–2000 demonstrated no significant difference in risk of endophthalmitis between the two types of cataract surgery [5] as did an analysis of all cases of endophthalmitis following cataract surgery at a Canadian hospital from 1989 to 1996 by Somani *et al.*[6] Castells *et al.* noted differences in complication rates between ECCE and phacoemulsification, but only for less serious complications, such as iris trauma, posterior capsule opacification, and corneal edema.[7]

In the early 1990s, phacoemulsification with intraocular lens implantation became the procedure of choice among cataract surgeons in most developed countries. Although small-incision phacoemulsification has remained the standard of care, surgeons continue to debate whether modifications in surgical technique have affected complication rates. For example, a meta-analysis of over 3 million cataract surgeries revealed higher rates of endophthalmitis in 2000–2003 than in 1990s. The higher rates in the later years were attributed to the transition from scleral tunnel to sutureless clear cornea incisions, which may serve as a conduit for microorganisms to gain entry into the eye. [8] However, in two more recent studies, rates of adverse events, including endophthalmitis, decreased among patients undergoing small-incision phacoemulsification. In the first study, Freeman *et al.*, in reviewing the records of 490,690 patients undergoing cataract surgery in Quebec between 1996 and 2005, found that postsurgical endophthalmitis was less common in the later study years than in the earlier years.[9•] The second study considered rates of severe events (endophthalmitis, retinal detachment (RD), suprachoroidal hemorrhage) among Medicare enrollees undergoing cataract surgery in 1994–1995, 1999–2000, and 2005–2006. Stein *et al.* found that the risk for complications was 21% higher in the 1994–1995 cohort than in the 2005–2006 cohort, and 20% higher in the 1999–2000 cohort than in the 2005–2006 cohort. [10••] In a separate analysis evaluating only the risk for endophthalmitis, the complication rate was lower in the 2005–2006 cohort than in the 1999–2000 cohort. Potential factors associated with the reduced rates of severe complications in more recent cohorts include innovations in phacoemulsification technology, the types of instruments available to better manage complex cases (pupil stretchers, capsular tension rings, dyes to stain the capsule), increased use of topical anesthesia, improvements in intraocular lenses, changes in preoperative or postoperative medication regimens, and better strategies to deal with intraoperative complications.

Risk Factors for Adverse Postsurgical Events

The next section focuses on patient- and surgeon-related variables that may affect the risk for postoperative events.

Patient-Related Factors

Age—In an analysis, using claims data from patients undergoing cataract surgery at Veterans Administration Medical Centers (VAMC) throughout the country, Greenberg *et al.* reported that older age (> 60 y) was associated with elevated odds of postsurgical complications.[11•] A separate analysis by the same authors found that event rates did not differ between octogenarians and nonagenarians.[12] In two other studies that considered possible risk factors in postoperative endophthalmitis, rates of this serious complication

were increased among the oldest patients.[9•,13] By contrast, using Medicare claims data from 1994–2006, after adjustment for confounding factors, Stein *et al.* found no association between patient age and the risk for post-cataract-surgery events.[10••]

Race—There is conflicting evidence on whether serious adverse events after cataract surgery vary by race. Using Medicare claims data from 1994–2001, West *et al.* found higher endophthalmitis rates among black patients than white patients.[13] More recently, Greenberg *et al.* reported that black veterans had a 38% increased odds of complications, compared with white veterans.[11•] In contrast, a review of Medicare claims data from 1994–2006 found no differences in the risks for adverse events between whites and other racial groups. In fact, the investigators noted that white men had higher rates of adverse events, compared with other groups.[10••] Directly comparing the results of these studies is difficult, however, because of differences in the time period of study, the location of the surgery, and the particular conditions classified as adverse events.

Sex—Several studies have reported increased rates of adverse postsurgical events among men. Using Canadian claims data from 1996–2006, researchers noted that men had 44% higher odds of postoperative endophthalmitis, compared with women.[9•] Similarly, Stein *et al.* found that men had a 23% higher risk for endophthalmitis and other severe events, compared with women.[10••] Narendran reported increased rates of posterior capsule rupture in men[14], and multiple investigators found elevated rates of pseudophakic RD in men.[15–19] Possible explanations for the higher complication rates in male patients include behavioral differences (e.g., adherence to postoperative instructions and antibiotic use)[20]; differences in bacterial flora between the sexes[21]; and use of α -antagonists, which can increase the surgical complexity, because they can lead to intraoperative floppy iris syndrome.[22]

Diabetes—Diabetes mellitus is a major public health problem, affecting over 9% of the U.S. population.[23] Researchers and surgeons are interested in learning whether patients with diabetes have increased risks for complications from cataract surgery. Among patients who underwent cataract surgery at VAMCs throughout the U.S., those with ophthalmological manifestations of diabetes had a 33% increased risk for complications, compared with other patients.[11•] A study using Medicare claims data found that the risk for cataract-surgery complications was associated with the severity of the underlying diabetic retinopathy. Patients with diabetes but no retinopathy and those with nonproliferative diabetic retinopathy had no difference in the risk for complications, compared with nondiabetic patients. However, patients with pre-existing proliferative diabetic retinopathy had a 62% increased likelihood of severe complications.[10••] Two possible reasons for the increased postsurgical risk for complications include altered immunity that may predispose patients with diabetes to infection, and increased complexity of cataract surgery resulting from poor pupil dilation, bleeding, and other complications.

α -Antagonist Use—In a population-based study, Bell *et al.* found that patients previously receiving tamsulosin—which has a known association with intraoperative floppy iris syndrome, a condition that can increase the complexity of cataract surgery—had a 133% elevated risk for adverse events.[22] In this study, no other α -antagonist, however, was associated with adverse postsurgical events.

Same-Day Combined Cataract/Other Intraocular Surgery—Occasionally surgeons perform same-day cataract surgery with another intraocular procedure, such as penetrating keratoplasty, trabeculectomy, or pars plana vitrectomy. Some surgeons prefer combined surgeries, rather than staging the two procedures separately, since this affords them the

opportunity to address two issues at once, without necessitating an additional trip to the operating room and a second exposure to the risks of anesthesia. Additionally, sometimes performing cataract surgery to facilitate the ability to perform the second surgery (e.g., when a dense cataract limits the ability to safely remove a concomitant vitreous hemorrhage) is necessary. Stein *et al.* found that those who underwent same-day combined surgery had a 151% increased risk for severe adverse events, compared with patients undergoing cataract surgery alone.[10••] Possible reasons for the higher complication rate associated with same-day combined surgery include the longer lengths of time in the operating room, exposure to additional instruments, and more incisions in the eye, all of which can increase the risk for adverse events, such as endophthalmitis. Furthermore, retrobulbar anesthesia use, additional manipulation of ocular tissues, and intraocular-pressure fluctuations during these combined cases may predispose patients to suprachoroidal hemorrhage. Additional research is needed to provide surgeons with evidence-based recommendations on whether same-day combined surgery is prudent when staging the two procedures is also an option.

Surgeon Factors

Surgeon Volume—A few studies have assessed the impact of surgeon volume on risk of complications from cataract surgery. Bell *et al.* compared rates of adverse events among surgeons throughout Quebec, Canada, who performed 50–250, 251–500, 501–1000, and >1000 cataract surgeries annually, finding complication rates of 0.8%, 0.4%, 0.2%, and 0.1%, respectively.[24] Odds of an adverse event were 70% lower among surgeons who performed 501–1000 surgeries and 86% lower among surgeons who performed >1000 surgeries a year relative to surgeons performing 50–250 cases annually. Fang *et al.* studied the relationship between surgeon volume and postoperative endophthalmitis after cataract surgery and found that low-volume surgeons had nearly double the rate of endophthalmitis as high-volume surgeons.[25] They also identified that hospital volume was also an important consideration with significantly fewer complications reported at high relative to low volume hospitals. A study assessing adverse events from 1996–2001 at the Sunderland Eye Infirmary also found a decrease rate of complications among surgeons with the highest surgical volume.[26] Furthermore, a review of 55,567 cataract surgeries performed by 404 surgeons during 2001–2006 demonstrated a lower rate of posterior capsule rupture among high volume surgeons.[27] Each of these studies showed that patients who undergo surgery by high volume cataract surgeons are less likely to experience adverse events relative to lower volume surgeons.

Surgeon Experience—Multiple investigators have studied rates of intraoperative and postoperative complications among cataract surgeries performed by resident surgeons. Retrospective chart reviews of resident cataract surgeries (the majority of which were phacoemulsifications) performed at 13 different residency training programs, with sample sizes ranging from 102 to 1442 patients, reported rates of posterior capsule rupture of 1.8% to 11.2%.[28–40] In two of these studies, lower complication rates were noted after the initial 50–80 procedures performed.[28,30] Recently, many residency training programs have been investing resources in surgical simulators, and some evidence indicates improved outcomes and reduced complications among trainees using this technology; therefore, a reassessment of these trends in the coming years could yield interesting results.[41]

Surgeon Case-Mix—Insurers, employers, and patients are increasingly interested in being able to compare outcomes among surgeons. Critics of such comparisons have noted, however, that if some surgeons are routinely caring for more complicated patients relative to others and this is contributing to higher rates of complications, it will appear as though they are worse surgeons relative to others who routinely operate on less complex patients. Stein *et al.* explored the influence of case-mix on adverse events following cataract surgery. They

found that individuals who received surgery by a surgeon whose patients generally tended to experience fewer serious adverse events relative to other surgeons had a 48% reduced risk of a severe adverse event relative to recipients of cataract surgery performed by surgeons whose patients, generally, were most prone to adverse events.[10••]. Habib *et al.* noted a relationship between surgical case-mix and volume; high-volume cataract surgeons tended to operate on patients with less complex cataracts, whereas low-volume surgeons were more likely to operate on more difficult cases.[42•] The findings of these studies emphasize the importance of accounting for surgical case-mix and volume when comparing outcomes among surgeons.

Specific Complications

Endophthalmitis

Endophthalmitis is a serious complication resulting from microorganisms gaining entry into the eye. Numerous studies have sought to identify the frequency of acute postoperative endophthalmitis, whether there has been an increase or decline in frequency with changes in surgical techniques, and risk factors that predispose patients to this complication. Estimates of postoperative endophthalmitis from eight large studies range from 0.05% to 0.30%. [2,3,6,9•,10••,43–45] Taban *et al.*, in a meta-analysis of the literature, identified 215 studies reporting postoperative rates of endophthalmitis after cataract surgery. Collectively, among the 3,140,650 patients undergoing cataract surgery, the endophthalmitis rate was 0.128%. [8] These authors stratified their results over time and noted decreasing endophthalmitis rates, from 0.327% in the 1970s to 0.158% in the 1980s and 0.087% in the 1990s. However, they noted a spike in endophthalmitis rates, up to 0.265%, during 2000–2003.[8] West *et al.* also noted higher rates of endophthalmitis in the late 1990s and early 2000s, relative to earlier years.[13] It is speculated the rise in endophthalmitis rates in the late 1990s to early 2000s may be attributable to the popularization of sutureless clear corneal incisions.[8] Two other groups reported reduced rates of postoperative endophthalmitis among surgeries in the mid-2000s relative to those performed in the late 1990s, suggesting sutureless incisions may not be the culprit. [9•,10••]

Several risk factors are known to be associated with endophthalmitis following cataract surgery. In multiple studies, rupture of the posterior capsule or need for anterior vitrectomy increases the risk of endophthalmitis considerably.[2,3,44–46] Other risk factors associated with endophthalmitis include age ≥ 85 years [3,9,13,44,45], male sex [2,3,9•,45], and ICCE compared with ECCE or phacoemulsification.[2,3] Black race [13], use of silicone instead of polymethylmethacrylate intraocular lenses[46], and nonuse of intracameral antibiotics [44] were found to increase the endophthalmitis risk in selected studies.

Suprachoroidal Hemorrhage

Suprachoroidal hemorrhage is a rare sight-threatening complication associated with incisional intraocular surgery. In the few studies that have quantified the incidence of suprachoroidal hemorrhage during or after cataract surgery, the rates have ranged from 0.03% to 0.13%. [10••,47–49] Ling *et al.* identified risk factors for poor prognosis following suprachoroidal hemorrhage including ECCE (vs. phacoemulsification), concomitant RD, massive hemorrhage, and apposition of the retina resulting from the hemorrhage.[48] In another series, risk factors associated with suprachoroidal hemorrhage included high myopia, glaucoma, diabetes, atherosclerotic vascular diseases, and hypertension.[50] Benzimra *et al.* reviewed data of 55,567 surgeries and found no increased suprachoroidal hemorrhage risk among blood thinning medication users.[51]

Retinal Detachment

Numerous studies have assessed the risk for RD after cataract surgery and the risk factors associated with pseudophakic and aphakic RD. Rates of RD after ICCE in the literature vary from 0.4% to 3.6%.^[52] Wetzig reported rates of RD to be 5 times higher in patients undergoing ICCE than in patients receiving ECCE.^[53] Post-ECCE rates of RD in the literature (0.55% to 1.65%) are similar to rates of RD after phacoemulsification (0.75% to 1.65%).^[52] Tuft *et al.* performed a case-control study with 249 patients with pseudophakic RDs and 845 matched controls who had cataract surgery and found that differing surgical technique (ECCE vs. phacoemulsification) was unrelated to RD.^[15] Likewise, Erie *et al.* reviewed all cataract surgeries performed in Olmstead County, Minnesota between 1980 and 2004 and found no significant difference in RD risk among patients undergoing ECCE, compared with phacoemulsification.^[16] Reviewing Medicare claims data from 1994–2006, Stein *et al.* reported a one-year postoperative rate of rhegmatogenous RD of 0.26%.^[10••] The study with the longest follow-up after cataract surgery to monitor for RD was conducted by Erie *et al.*, who reported a 1.79% cumulative probability of RD at 20 years after surgery.^[16]

Several risk factors are known to be associated with pseudophakic RD—including, especially, intraoperative tear of the posterior capsule. Tuft *et al.* reported nearly a twentyfold-increased odds of RD after cataract surgery when there is a rupture of the posterior capsule.^[15] The large Rotterdam cohort study also reported considerably higher rates of RD in cases which are complicated by a break in the posterior capsule.^[18] Other factors that increase the risk for pseudophakic RD include younger age [15–18], male sex [15–19], axial myopia [15–19,54,55], zonular dehiscence^[15], a history of RD in the contralateral eye [15,54], and a history of ocular trauma after cataract surgery.^[54] Evidence on whether subsequent neodymium:yttrium–aluminum–garnet laser posterior capsulotomy increases the risk for pseudophakic RD is conflicting, with some studies demonstrating an increased risk [52,54], but others not.^[15,56]

Posterior Capsule Rupture

The most common intraoperative complication associated with cataract surgery is disruption of the posterior capsule, which can lead to vitreous loss, the need for vitrectomy, placement of the intraocular lens in the ciliary sulcus or anterior chamber, and occasionally the need for additional surgical interventions. Two recent large-scale studies have quantified the proportion of patients experiencing posterior capsule rupture during cataract surgery. Reviewing data on 55,567 cataract surgeries during 2001–2006 in the United Kingdom, Narendran *et al.* reported that 1.9% of patients experienced disruption of the posterior capsule.^[14] Using data from 45,082 patients who underwent cataract surgery at a VAMC between 2005 and 2007, Greenberg *et al.* reported that 3.5% of patients had this complication.^[11•] Differences in rates of posterior capsule rupture between these studies may be attributable to patient-related factors (ex: differences in case-mix, ratio of males to females), surgeon-related factors (e.g., proportion of surgeries performed by trainees), or other factors. In the study by Narendran, risk indicators for posterior capsule rupture included increasing age, male sex, comorbid glaucoma, diabetic retinopathy, brunescence/white cataract, poor view of the fundus, exfoliation syndrome/phacodonesis, small pupil size, axial length >26.0 mm, -antagonist use, an inability to lie flat, and trainee surgeons performing operations.^[14]

Conclusion

Researchers continue to look for innovative ways of improving the efficiency, safety profile, and functional patient outcomes of cataract surgery. As technological advances, such as

microincision cataract surgery, femtosecond laser assisted cataract surgery, and the use of multifocal intraocular lenses, continue to gain popularity, we will learn whether surgeons can achieve further reductions in the already low rates of adverse events associated with this procedure.

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