·Clinical Research·

Risk factors for endophthalmitis following cataract surgery–our experience at a tertiary eye care centre in India

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Abstract

• **AIM: To determine the risk factors for acute endophthalmitis after cataract extraction in a tertiary care centre in India.**

• **METHODS: We performed a nested case control study within a retrospective cohort. The surgical records of all patients with clinically diagnosed endophthalmitis within one month after cataract surgery, performed between January 2006 and December 2009, were reviewed. These were compared with randomly selected age and gender–matched controls, from patients having routine cataract surgery within ±1wk of the endophthalmitis case. Univariable and multivariable analysis were performed to identify risk factors for endophthalmitis.**

• **RESULTS: Of the total 33 856 cataract surgeries performed during this period, there were 57 cases of postoperative acute endophthalmitis that met our study criteria. Thus, the overall incidence of endophthalmitis in our cohort was 1.6 per 1000 cataract extractions performed. Mean age of cases was 55.9y (SD: 10.9y) and for controls was 55.6y (SD: 9.8y). Thirty–five cases (61.4%) and 133 controls (59.6%) were males. Median time of onset of endophthalmitis was 4d (IQR 2–9d; range: 1–30d). Thirty–nine cases (68.4%) presented within 7d and 27 cases (47.4%) were culture positive. Two hundred and twenty–three age and gender matched controls were selected. In multivariate analysis, endophthalmitis was associated with posterior capsular rupture (PCR) during surgery (OR 6.98, 95%CI: 2.22–21.98), phacoemulsification *via* scleral incision with a foldable intraocular lens (IOL) implantation (OR 3.02, 95%CI: 1.13–8.04) and ocular co–morbidity (OR 2.32, 95%CI: 1.11–4.87).**

• **CONCLUSION: PCR, presence of ocular co–morbidity, and phacoemulsification *via* scleral incision with foldable–IOL were found to be independent risk factors for acute endophthalmitis.**

• **KEYWORDS:** endophthalmitis; incidence; cataract surgery; risk factors
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INTRODUCTION

There has been a quantum leap in the technique of cataract surgery in recent times as well as in chemoprophylaxis, but infection (endophthalmitis) continues to affect the outcome in approximately 1 in 500 cases [1]. The risk of endophthalmitis in a literature search of the past twenty years reportedly ranges between 0.02% and 0.8%[2-9] and although endophthalmitis appears to be an infrequent complication, it is a major cause of post-cataract surgery blindness[10]. Various studies have been conducted, mainly on Caucasian populations, which have identified risk factors pertaining to patient [4,5,11,12], surgeon [4,5,13,14] and surgical characteristics [2-5,13-17] but there is little consistency of results between these studies.

Patient characteristics giving rise to increased risk for developing post operative endophthalmitis include-increasing age[4,18], male gender[5,18], left eye operation[12] and uncontrolled diabetes mellitus [11], among others. Surgical characteristics pertaining to chemoprophylaxis most often resulting in a decreased risk of post operative endophthalmitis are the use of preoperative povidone-iodine antisepsis [19], sub-conjunctival antibiotics [13,14] and intracameral cefuroxime[5]. Rupture of the posterior capsule (PCR) with vitreous loss and increased surgical time do appear recurrently as factors most often implicated in the development of this catastrophic side effect [2-5,8,9,13,14,17]. In the meantime the debate on the role of wound location, cornea *vs* sclera, rages on[3-5].

With increasing volumes of surgery and reduced time to accomplish it, topical anaesthesia has firmly rooted itself into modern day surgery but not without some concern; recent results suggest there is an association between topical anaesthesia and endophthalmitis after cataract surgery [3]. Choice of intraocular lens (IOL) implant too may have a bearing; silicone optics[5,17] and polypropylene haptics[2] have come under the scanner, as indeed has the grade of the surgeon[5,13].

In view of limited availability of data from south-east Asia region and an effort to better identify risk factors for postoperative endophthalmitis in our cohort, we used the epidemiologic methodology of case-controlled study within a retrospective cohort.

SUBJECTS AND METHODS

The Institutional Review Board at LV Prasad Eye Institute (LVPEI) approved this study and it was conducted in accordance with the tenets of the Declaration of Helsinki.

We performed a retrospective case-note review of all patients with acute postoperative endophthalmitis following cataract surgery [phacoemulsification and small incision cataract surgery (SICS)], both culture positive and negative, at our tertiary level academic practice over the study period of January 2006 to December 2009. We only considered subjects with a primary removal of an age related cataract at LVPEI, and a documented 30d post cataract surgical removal follow up at the institute as eligible for inclusion. Patients undergoing the procedure elsewhere, combined procedures with filtration and corneal transplantation, post-traumatic and paediatric cataract extractions were all excluded.

Index Case We defined an index case as an individual who developed endophthalmitis within 30d of the primary cataract surgical procedure. Endophthalmitis, for this study, was defined based on clinical criteria that included pain, loss of vision, presence of hypopyon or membrane over pupil, and vitreous opacities presenting within a month of the surgery. This was confirmed by a documented comprehensive ophthalmic examination including anterior and posterior segment; latter was documented following full dilatation. B-mode ultrasound was done if vitreous inflammation precluded the view of the fundus. This rigorous documentation was confirmed by the primary surgeon and all cases were then reviewed jointly by the primary surgeon and a retina specialist. Subsequently all these patients underwent vitreous tap and/or vitrectomy along with injection of antibiotics.

Controls We defined a control as an individual who had undergone primary removal of the lens for age related cataract, between January 2006 and December 2009, who did not meet any of the exclusion criteria as above, and did not have any signs or symptoms associated with endophthalmitis within 30d of cataract surgery. A control group, age and gender matched, of 223 patients (approximately four for each index case of endophthalmitis) was randomly selected using random systematic sampling technique from among the 33 856 patients who underwent routine lens extraction for age related cataract, within ±1wk of the index case and met all criteria for a control.

We examined the following variables in both case and control groups:

1) Patient characteristics: rural/urban, systemic co-morbidity including history of diabetes and hypertension, ocular co-morbidity including presence of adnexal and ocular surface problems (*e.g.* sac disease, pterygium), corneal problems (*e.g.* scars and degeneration), glaucoma and retinal problems (*e.g.* proliferative diabetic disease, vascular occlusions).

2) Surgical characteristics: type of cataract (mature, immature), type of anaesthesia (per-bulbar versus topical), type of surgery (phacoemulsification, self-sealing SICS), wound location (corneal, scleral), IOL optic material (foldable and non-foldable), PCR, subconjunctival antibiotics.

The type of surgery done was investigated along the following lines: phaco with foldable IOL, *via* corneal and scleral incisions, and phaco with non-foldable IOL *via* scleral route. SICS, which can only be done *via* sclera, was the fourth group where non-foldable IOL was used. It may appear counter-intuitive to do phaco surgery and use non-foldable IOL; however this is the favoured approach in the vast majority of surgeries that are done free-of-cost, a significant proportion of the Institute's work-load, in order that it be delivered in a cost-effective manner to eliminate needless blindness due to cataract in a developing country.

3) Surgeon characteristics: experience *i.e.* whether performed by a consultant or a trainee/fellow.

We performed Student's t-test for continuous variable, Fisher's exact test for categorical variable and conditional logistic regression for risk factor analysis. We performed univariable analysis to identify risk factors for endophthalmitis. Factors that were thought as confounders were included in multivariable analysis to explore risk factors for endophthalmitis further, to obtain odds ratio (OR), 95% confidence intervals (CIs) and P-values for the association between the selected variables and endophthalmitis. All analyses were done using Stata 11[20].

RESULTS

During the study period, the participating surgeons performed 33 856 cataract surgeries for age-related cataracts; 8226 surgeries were done in 2006, 8750 surgeries were done in 2007, 9471 in 2008 and 7409 in the year 2009. Fifty-seven patients of postoperative acute endophthalmitis that met our study criteria were identified. Thus, overall incidence of endophthalmitis in our cohort was 1.6 per 1000 cataract

extractions performed, a risk of 0.16%. This included 14 cases in 2006, 16 cases in 2007, 21 cases in 2008 and 6 cases in 2009. The annual risk was 0.17% (95% CI: 0.16-0.18), 0.18% (95%CI: 0.17-0.19), 0.22% (95%CI: 0.21-0.23) and 0.08% (95%CI: 0.07-0.09) in the years 2006, 2007, 2008 and 2009 respectively. Thus 57 index cases of endophthalmitis were compared to 223 controls.

Mean age of cases was 55.9y (SD: 10.9y) and for controls was 55.6y (SD: 9.8y). Thirty-five cases (61.4%) and 133 controls (59.6%) were males. Median time of onset of endophthalmitis was 4d (IQR 2-9d; range: 1-30d). Thirty-nine cases (68.4%) presented within 7d and 27 cases (47.4%) were culture positive.

Table 1 shows the total number of cases and controls used for univariable and multivariable analysis.

Table 2 shows the result of univariable and multivariable analysis. In univariable analysis (Table 2), there was increased risk of endophthalmitis with presence of ocular co-morbidity (P=0.01), phaco *via* the scleral route with foldable lens (P=0.001) and posterior capsular rupture (P <0.001). The risk of endophthalmitis was lower in phacoemulsification with non-foldable lens *via* scleral route (P =0.01). In multivariable analysis (Table 2), there was increased risk of endophthalmitis with the presence of ocular co-morbidity (P=0.03), the occurrence of posterior capsular rupture during surgery (P=0.001) and having undergone phacoemulsification with scleral incision and foldable lens insertion (P=0.03) were independent risk factors. Adjusted odds ratios for each of these factors were 2.32 (95% CI: 1.11-4.87), 6.98 (95% CI: 2.22-21.98) and 3.02 (95% CI: 1.13-8.04) respectively. A trend towards lower risk was seen when phacoemulsification was done *via* a scleral incision followed by non-foldable lens implantation. This however did not reach significance (P=0.08). Another factor that demonstrated trend towards higher risk was when a trainee operated (P=0.08), but this too did not reach significance.

Table 1 Potential risk factors for post-operative endophthalmitis

Variables	Controls	Cases	*P*
Place of residence			
Urban	152	44	
Rural	71	13	0.12
Ocular co-morbidity[1]			
No	159	31	
Yes	62	26	0.01
Systemic co-morbidity[2]			
No	140	34	
Yes	82	23	0.64
Type of anaesthesia			
Topical	41	5	
Local	182	52	0.09
Type of cataract			
Immature	180	48	
Mature	43	9	0.57
Type of surgery			
Phaco-foldable corneal	68	13	
Phaco-foldable scleral	41	22	0.001
Phaco-non foldable scleral	42	2	0.01
SICS-non foldable scleral	69	20	0.56
Surgeon			
Consultant	145	34	
Trainee	77	23	0.43
Posterior capsular rupture			
No	211	44	
Yes	10	13	<0.001
Subconj antibiotics			
No	200	52	
Yes	23	5	0.63

[1]Ocular co-morbidity factors included adnexal and surface diseases, presence of glaucoma and retinal diseases among others; [2]Systemic co-morbidity factors included history of hypertension, diabetes, coronary artery disease, asthma *etc*.

DISCUSSION

Overall incidence of acute endophthalmitis in our cohort was 1.6 per 1000 cataract extractions performed, a risk of 0.16%. Overall risk seemed to be very consistent with the risk seen over a decade ago, in the same population, with endophthalmitis occurring at a risk of 1.7 per 1000 cataract extractions [21]. There was a sharp drop in the risk of endophthalmitis in the last year of our study period-this is accounted by the commencement of the practice of intracameral cefuroxime in cases of PCR following convincing evidence published by European Society of Cataract and Refractive Seeurgery (ESCRS) [5]. Similar decrease was also shown by the group in Singapore[18].

Endophthalmitis was significantly associated with the presence of ocular co-morbidity. Ocular and systemic co-morbidity factors were grouped together as individually they occurred infrequently; only ocular comorbidity factors were found to be a significant independent risk factor. Previous studies have reported diabetes as a key risk factor[11]. By far the most significant intra-operative risk factor in our cohort is the occurrence of PCR with or without vitreous loss, in agreement with several studies [4,9,14,17,22,23].

Contrary to our experience with this cohort, there have been several reports of clear corneal incision in phaco surgery being risk factors for acute post-cataract surgery endophthalmitis when compared with scleral tunnel incisions[3-5,24,25]. It was also baffling to note that OR for scleral approach phaco with foldable IOL, versus using a non-foldable IOL, was a significant risk factor in our cohort. On further exploration, we found that though there were numerous brands of foldable acrylic IOLs' that were implanted, over 70% of those implanted *via* scleral incision that developed endophthalmitis were hydrophillic lenses, and 50% of these were culture positive. All non-foldable IOLs'

Table 2 Univariable and multivariable analysis of potential risk factors for post-operative endophthalmitis

Variables	Univariable analysis	*P*	Multivariable analysis	*P*
Place of residence				
Urban	Ref		Ref	
Rural	0.54 (0.26-1.17)	0.12	0.77 (0.28-2.14)	0.6
Ocular co-morbidity[1]				
No	Ref		Ref	
Yes	2.15 (1.18-3.91)	0.01	2.32 (1.11-4.87)	0.03
Systemic co-morbidity[2]				
No	Ref		Ref	
Yes	1.16 (0.63-2.13)	0.64	1.24 (0.56-2.73)	0.51
Type of anaesthesia				
Topical	Ref		Ref	
Local	2.33 (0.87-6.21)	0.09	1.67 (0.52-5.36)	0.4
Type of cataract				
Immature	Ref		Ref	
Mature	0.8 (0.37-1.74)	0.57	0.87 (0.33-2.28)	0.77
Type of surgery				
Phaco-foldable corneal	Ref		Ref	
Phaco-foldable scleral	3.24 (1.61-6.51)	0.001	3.02 (1.13-8.04)	0.03
Phaco-non foldable scleral	0.16 (0.04-0.66)	0.01	0.22 (0.04-1.20)	0.08
SICS-non foldable scleral	1.21 (0.6-2.28)	0.56	1.05 (0.34-3.26)	0.94
Surgeon				
Consultant	Ref		Ref	
Trainee	1.28 (0.69-2.40)	0.43	2.45 (0.9-6.6)	0.08
Posterior capsular rupture				
No	Ref		Ref	
Yes	7.16 (2.68-1916)	<0.001	6.98 (2.22-21.98)	0.001
Subconj antibiotics				
No	Ref		Ref	
Yes	0.77 (0.27-2.21)	0.63	0.4 (0.1-1.57)	0.19

[1]Ocular co-morbidity factors included adnexal and surface diseases, presence of glaucoma and retinal diseases among others; [2]Systemic co-morbidity factors included history of hypertension, diabetes, coronary artery disease, asthma *etc*.

were polymethyl methacrylate (PMMA) lenses; when these were implanted in phaco surgery, smaller diameter optic was preferred as compared to larger diameter in SICS surgery.

In most cases, it is felt that contamination of the IOL occurs prior to implantation as a result of contact with external ocular tissue [26,27]. Consequently, the facility or mediator with which bacteria adhere to the IOL surface is considered to be an important factor in the development of this complication. In 2003, Schauersberger *et al* [25] studied *in vitro* bacterial adherence, to several categories of IOLs' that included four types of rigid IOLs (PMMA and heparin coated PMMA) and five types of foldable IOLs, both hydrophobic and hydrophilic. They found that the greater the hydrophilic nature of the IOL material, the lower the early adhesion for bacteria and concluded that the use of hydrophilic IOLs in conjunction with adequate surface anti-microbial chemoprophylaxis immediately before surgery, could reduce the incidence of endophthalmitis. In sharp contrast to this finding by Schauersberger *et al* [25], in our cohort an overwhelming majority of foldable IOLs used in cases that developed endophthalmitis were hydrophilic in nature. In an endophthalmitis outbreak of eleven cases over a period of 3wk at our institute, unrelated to our study period, the contamination of a particular brand of foldable hydrophilic acrylic IOLs' was proven [27]. Thus hydrophilic nature of an acrylic IOL does not appear to be any less susceptible to bacterial contamination.

The degree of maturity of the cataract did not appear to influence the incidence of endophthalmitis; neither did the type of anaesthesia. However OR for local *i.e.* peri-ocular *vs* topical anaesthesia was 2.33 (95%CI: 0.87-6.21) (P=0.09) in univariable analysis but this was not found to be significant in the multivariable model. Contrary to our findings there have been reports of increased incidence of endophthalmitis when topical anaesthesia has been used[3,28].

Surgeon experience is an important factor in the incidence of complications during cataract surgery[29]. Though the OR of a trainee operating is relatively high, this did not reach

statistical significance. Another study conducted by Aravind Eye Care System (AECS) also did not find any statistical difference in the incidence of endophthalmitis between surgeon groups [30].

Chemoprophylaxis has been a controversial issue in cataract surgery with pre-operative povidone-iodine, in the conjunctival sac and applied over per-ocular skin, being the only standardised procedure, possibly the world over, following strong support from literature [19]. Other forms of chemoprophylaxis, including antibiotics in irrigating fluid, subconjuctival antibiotics after the operation and intra-cameral antibiotics have all come under the scanner by various authors, and have had varied results [5,31]. At our tertiary centre use of antibiotics in the irrigating fluid is not routine and use of intra-cameral antibiotics was also not routine prior to 2009. However use of subconjunctival antibiotics is, and has been, intermittent and at the discretion of the surgeon. It did appear to render a degree of protection without reaching significance. In the nation-wide case-controlled study of endophthalmitis in UK, Kamalarajah *et al* [14] also found administration of subconjunctival antibiotics, at the end of surgery, imparting a protective effect against development of endophthalmitis. Lehmann *et al*[15] seemingly confirmed this in a study done at a single Ophthalmic unit in the same country well before the nation-wide study.

As with all retospective studies, there are certain inherent limitations in our study too. Furthermore, it is not a population based study; on the contrary it is a study based in a advanced tertiary centre and it is quite probable that the profile of patients who are referred are systemically more debilitated and likely have types of cataract that ophthalmologists are unwilling to take on in the community for very understandable reasons. We also found that hydrophilic IOLs were implicated, contrary to literature, and hence we surmise that the material of the IOL cartridge and or injector should also be brought under the scanner. Thus it is quite possible that due to non-availability of data, some factors may have been heightened whilst others may be attenuated.

Nonetheless we present findings in predominantly south Indian eyes at this tertiary eye centre, some risk factors which have agreement with western and other Asian populations (posterior capsular rupture), whilst others do not (ocular co-morbidity, scleral tunnels with hydrophillic IOL). We recommend prospective data collection of all possible confounders, factors that could not be adjusted for in our study.

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