

Incidence of Endophthalmitis Following Cataract Surgery and Risk Factors: Retrospective Study Using the IRIS Registry

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FINANCIAL DISCLOSURES

Michael H. Goldstein, MD; Srilatha Vantipalli, PhD; and Jamie L. Metzinger, MPH are employees of Ocular Therapeutix, Inc.

Deepinder K. Dhaliwal, MD and Andrew A. Moshfeghi, MD are consultants for Ocular Therapeutix Inc.

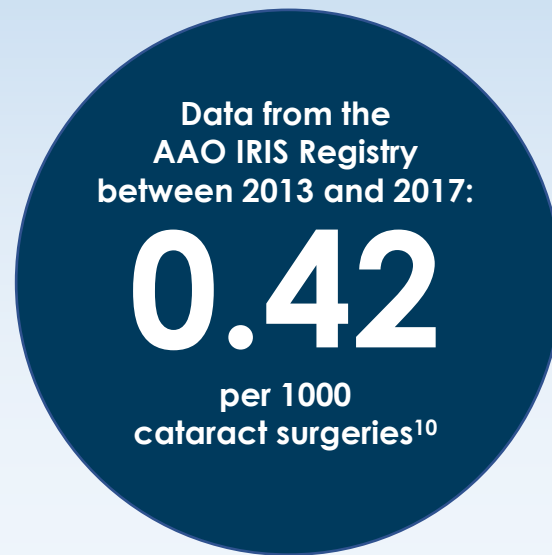
Helene Fevrier, MPH is an employee of Verana Health

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Background and Rationale

Endophthalmitis Following Cataract Surgery

- Endophthalmitis after cataract surgery is rare, but visually devastating if not treated early and properly
- Its very low incidence necessitates a large sample size to conduct meaningful studies



AAO IRIS® (Intelligent Research In Sight) Registry¹¹

- Clinical registry with aggregated real-world data from nearly 60 million unique patients
- Approximately 16,000 ophthalmologist and associated ophthalmic clinicians contribute data to the registry through an EHR

The IRIS Registry is an ideal database to assess rare events like endophthalmitis following cataract surgery

AAO, American Academy of Ophthalmology; IRIS, Intelligent Research in Sight

References. 1. Freeman EE, et al. *Arch Ophthalmol.* 2010;128(2):230-234. 2. Hatch WV, et al. *Ophthalmology.* 2009;116(3):425-430. 3. Javitt JC, et al. *Arch Ophthalmol.* 1991;109(8):1085-1089. 4. Lundstrom M, et al. *Acta Ophthalmol Scand.* 2002;80(3):248-257. 5. Morlet N, et al. *Br J Ophthalmol.* 2003;87(5):574-576. 6. Norregaard JC, et al. *Br J Ophthalmol.* 1997;81(2):102-106. 7. Somani S, et al. *Can J Ophthalmol.* 1997;32(5):303-310. 8. Stein JD, et al. *Ophthalmology.* 2011;118(9):1716-1723. 9. Stein JD. *Curr Opin Ophthalmol.* 2012;23(3):219-225. 10. Pershing S, et al. *Ophthalmology.* 2020;127(2):151-158. 11. IRIS Registry Data Analysis. American Academy of Ophthalmology. <https://www.aao.org/iris-registry/data-analysis/requirements>. Accessed April 1, 2021.

Methods

Study Design

Study Design

- Retrospective study
- Data from the AAO's IRIS Registry with analyses conducted by Verana Health

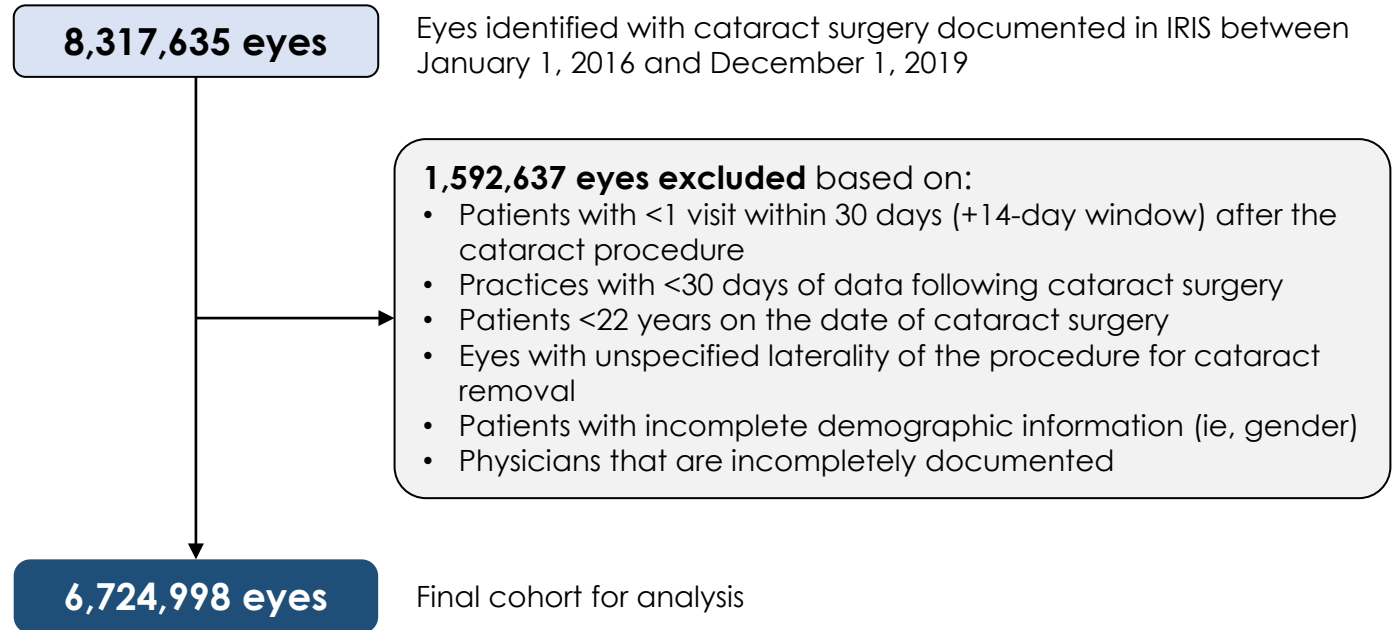
Key Inclusion Criteria

- Extracapsular cataract removal with insertion of intraocular lens prosthesis between January 1, 2016 and December 1, 2019
- At least one visit within 30 days of surgery
- ≥22 years of age

Objective

- To identify the incidence of endophthalmitis within 30 days of any cataract surgery in the United States

Identification of Patient Eyes



Results

Baseline Demographics

	All patient eyes (N=6,724,998)
Mean age (SD), years	70.91 (8.95)
Sex, n (%)	
Male	2,762,441 (41.1%)
Female	3,962,557 (58.9%)
Race, n (%)	
White	4,927,456 (73.3%)
Black	429,787 (6.4%)
Asian	151,199 (2.2%)
Native American/other Pacific	34,833 (0.5%)
Multirace	27,539 (0.4%)
Unknown	1,154,184 (17.2%)
Concurrent procedures, n (%)	
Glaucoma procedures	241,840 (3.6%)
Vitreous procedures*	30,591 (0.5%)
History of diabetes, n (%)	1,528,966 (22.7%)
Nonproliferative diabetic retinopathy	247,918 (3.7%)
Proliferative diabetic retinopathy	88,381 (1.3%)
Diabetic macular edema	112,280 (1.7%)

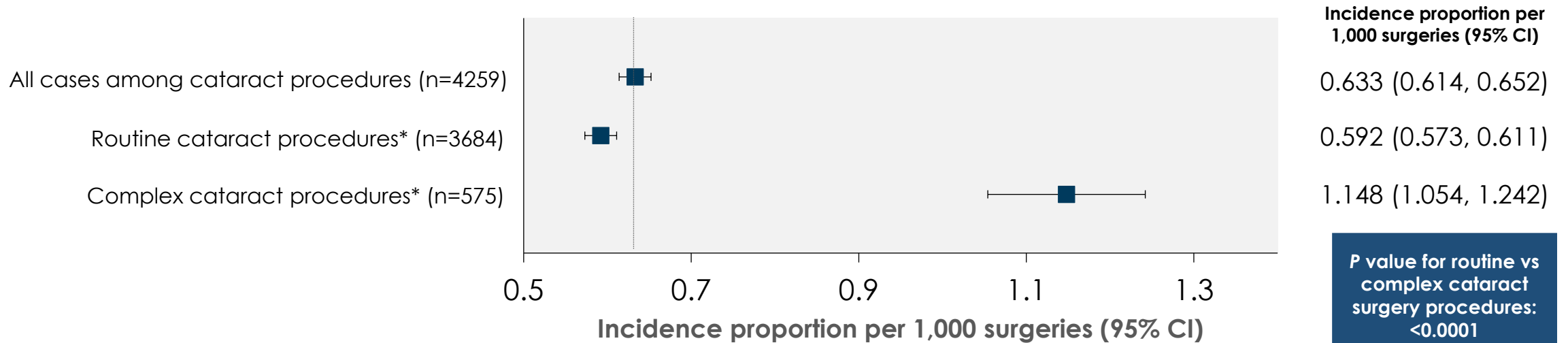
* Includes anterior vitrectomy and pars plana vitrectomy

	All patient eyes (N=6,724,998)
Region, n (%)	
Midwest	1,352,395 (20.1%)
North	837,423 (12.5%)
South	2,484,111 (36.9%)
West	1,155,755 (17.2%)
Unknown	895,314 (13.3%)
Cataract Surgery Type, n (%)	
Routine	6,224,189 (92.6%)
Complex	500,809 (7.4%)
Cataract Type, n (%)	
Congenital Cataract	1,219 (0.02%)
Cortical Cataract	808,103 (12.0%)
Traumatic Cataract	8,770 (0.1%)
Nuclear Sclerotic Cataracts	4,485,219 (66.7%)
Posterior Subcapsular Cataracts	524,435 (7.8%)

Results: Overall Incidence of Endophthalmitis

Incidence of endophthalmitis was low at 0.633 cases per 1,000 cataract surgeries (95% CI: 0.614, 0.652)

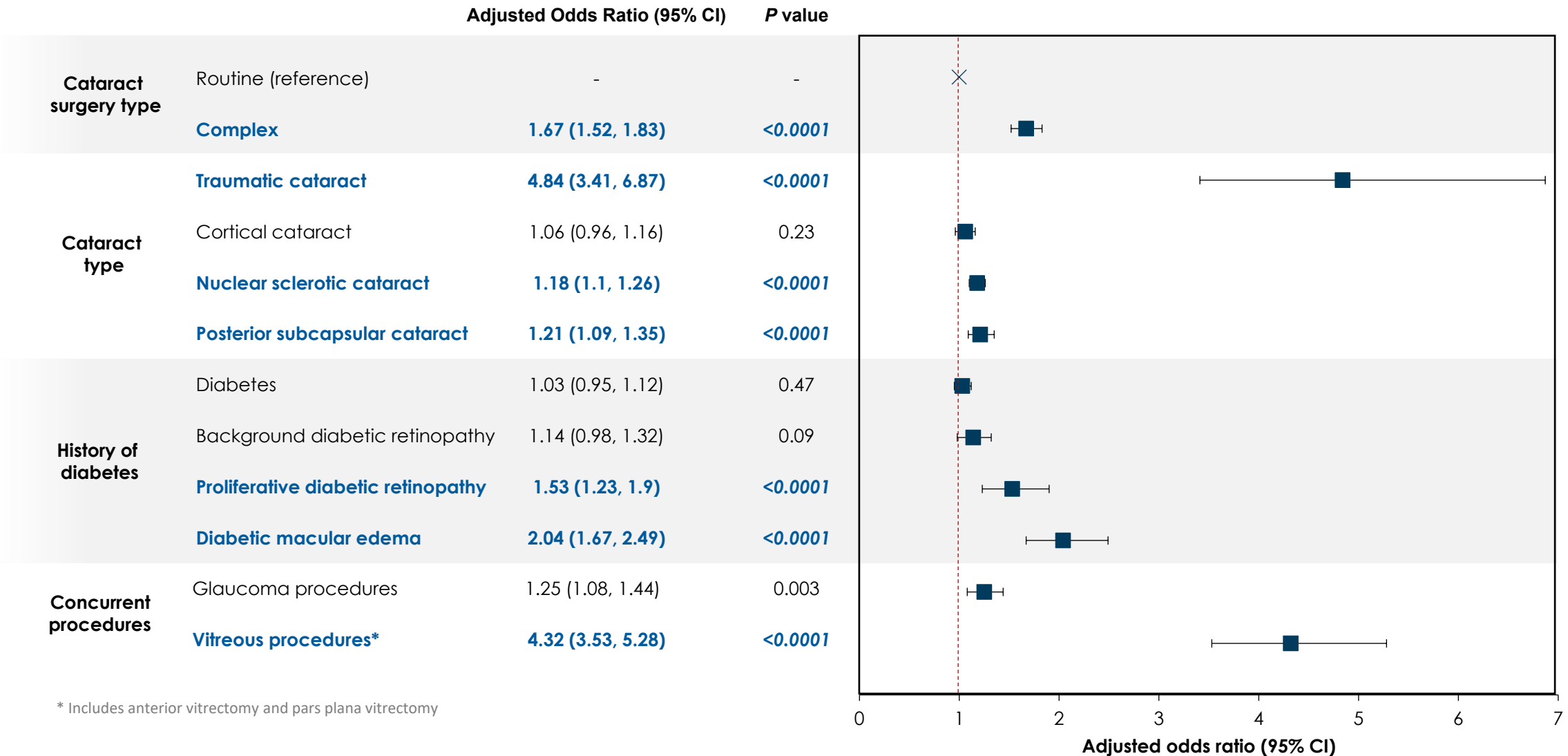
Incidence of Endophthalmitis Among All, Routine and Complex Cataract Procedures



*Among 4259 endophthalmitis cases identified

Results: Clinical Risk Factors for Endophthalmitis

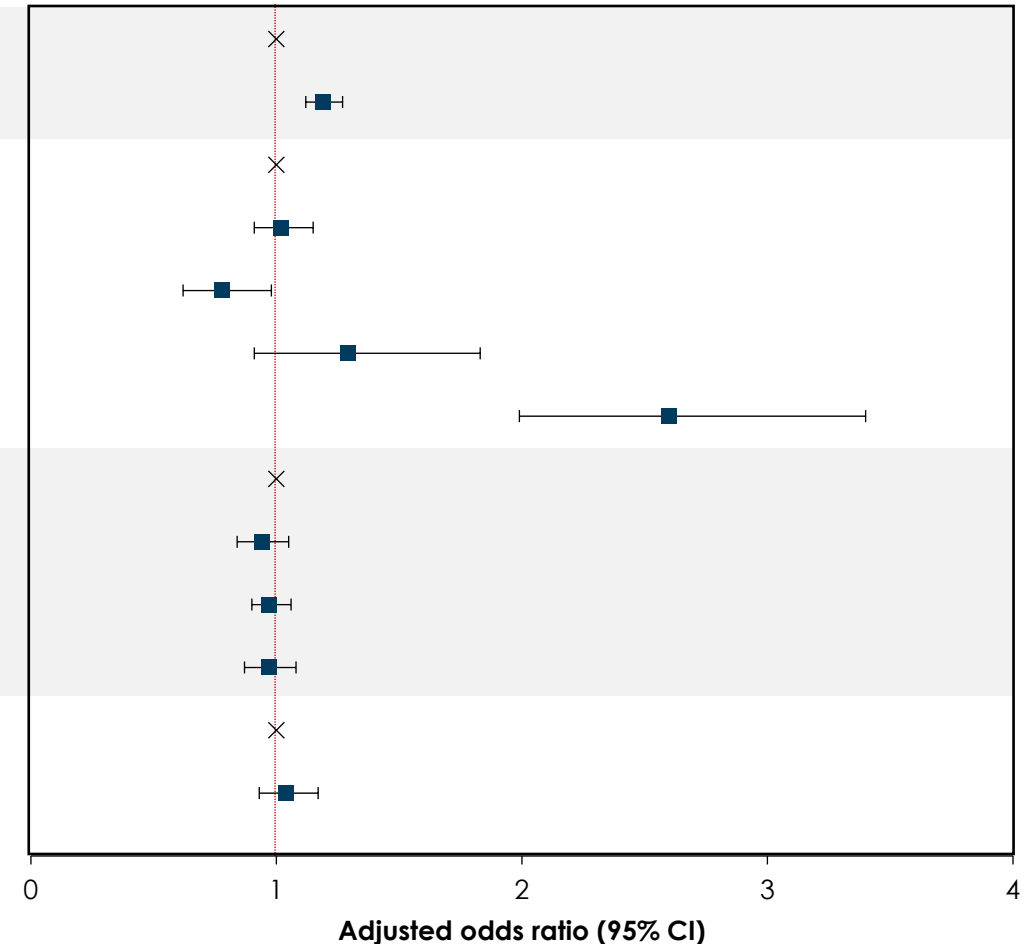
Traumatic cataract, concurrent vitreous procedures and history of DME increased the odds of endophthalmitis



Results: Demographic Risk Factors for Endophthalmitis

Adjusted Odds Ratio
(95% CI) P value

		Adjusted Odds Ratio (95% CI)	P value
Sex	Female (reference)	-	-
	Male	1.19 (1.12, 1.27)	<0.0001
Race	White (reference)	-	-
	Black	1.02 (0.91, 1.15)	0.72
	Asian	0.78 (0.62, 0.98)	0.03
	Native American and other Pacific*	1.29 (0.91, 1.83)	0.15
	Multiracial*	2.60 (1.99, 3.40)	<0.0001
Region	Midwest (reference)	-	-
	North	0.94 (0.84, 1.05)	0.28
	South	0.97 (0.90, 1.06)	0.54
	West	0.97 (0.87, 1.08)	0.56
Setting	Urban (reference)	-	-
	Rural	1.04 (0.93, 1.17)	0.46



* Represents ≤0.5% of study population

Conclusions

These data represent **one of the largest recent analyses** of acute postoperative endophthalmitis following cataract surgery

- This retrospective study analyzed a total of **6,724,998 eyes** from the IRIS Registry database
- Average age (SD) of subjects at time of cataract extraction was 70.91 (8.95) years

Overall, the **incidence of post-cataract surgery endophthalmitis between 2016 to 2019 was low** which is consistent with prior studies

- The overall incidence of endophthalmitis among all cases was **0.633 per 1,000 surgeries** (95% CI: 0.614, 0.652)

Risk factors such as **traumatic cataracts, concurrent vitreous procedures, history of diabetic macular edema or proliferative diabetic retinopathy** and **complex cataract surgeries** were associated with statistically significantly higher rates of endophthalmitis incidence ($P < 0.0001$)