

Article

Incidence and Characteristics of Endophthalmitis after Cataract Surgery in Poland, during 2010-2015

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Abstract: *Background:* The assessment of the incidence and characteristic of acute and chronic post-operative endophthalmitis (POE) after cataract surgery in Poland during 2010 - 2015. *Patients and methods:* All hospitalizations of patients, in the National Database of Hospitalizations, who underwent cataract surgery alone or in combined procedures in Poland between January 2010 and December 2015, with a billing code of endophthalmitis, were selected. Acute endophthalmitis was identified if symptoms occurred within 1 - 42 days from the cataract surgery and chronic endophthalmitis if symptoms occurred ≥ 43 days after cataract surgery, respectively. *Results:* In total, 1331 cases of POE after 1,218,777 cataract extractions were identified. The overall incidence of POE decreased from 0.125% in 2010 to 0.066% in 2015. In multiple logistic regression analyses, increasing age was significantly associated with acute POE, while type II diabetes mellitus, extracapsular cataract extraction and one-day surgery were significantly associated with chronic POE. The combined cataract surgery and male sex were significant risk factors for both acute and chronic POE. A total of 62.51% of all eyes affected by POE received antibiotic treatment and 37.49% had vitrectomy treatment. *Conclusions:* During the study period, the total incidence of post-operative endophthalmitis after cataract surgery decreased significantly.

Keywords: cataract surgery; acute endophthalmitis; chronic endophthalmitis

1. Introduction

Postoperative endophthalmitis is a serious complication of cataract surgery, with the incidence varying from 0.02% to 0.71% according to the recent studies. Those studies also revealed a significant decline in the incidence of postoperative endophthalmitis in the twenty-first century [1,2]. The results of the European Association of Cataract and Refractive Surgeons (ESCRS) report showed that the use of intracameral cefuroxime at the end of the cataract surgery significantly reduced the occurrence of postoperative endophthalmitis as well as improved the surgery techniques with the use of injectable lenses, topical anesthesia and microincisions [3]. According to this report, the existing risk factors for postoperative endophthalmitis included clear corneal incisions, the use of silicone intraocular lenses,

and the presence of surgical complications [3]. Although the ESCRS endophthalmitis report was based on multicenter, international study and comprised 16603 participants, its results have been published over a decade ago. [3]

Globally, cataract surgery is the most common ocular surgery; however, reports on the incidence of endophthalmitis after cataract based on national basis are limited [4,5]. In 2013, Friling et al. [6] reported the incidence of endophthalmitis in the Swedish National Cataract Register from 2005 to 2010. In 2016, Creuzot-Garcher et al. [7] reported the incidence of acute postoperative endophthalmitis in France from 2005 to 2014. Two studies from Canada [8,9] published data from the State Control for Health Insurance Plan regarding all cataract surgeries performed in 1996 -2005 in Quebec province, and during 2002-2006 in Ontario province . The aim of the present study was to assess the incidence and characteristic of endophthalmitis after cataract surgery in overall population of Poland from 2010 to 2015. Our study was part of a project titled "Maps of Healthcare Needs - Database of Systemic and Implementation

Analyses," which was co-financed by the European Union funds through the European Social Fund under the Operational Programme Knowledge, Education and Development [10].

2. Materials and Methods

In Poland, the National Health Fund (Narodowy Fundusz Zdrowia - NFZ) maintains the national database of hospitalizations, which records all medical procedures in public and private hospitals financed from public sources. The national database of hospitalizations provides accurate population-based medical data which include the diagnoses coded according to the International Classification of Diseases, 10th Revision (ICD-10), and all procedures performed, coded using the International Classification of Diseases, 9th Revision, ICD-9 procedure codes and unique NFZ codes corresponding to certain hospital procedures. It compiles also the socio- demographic data of all patients including personal identification number (PESEL), age, sex and place of residence. Our study design was a population-based retrospective epidemiological survey. The subject sampling method was published in our previous studies. In brief: "the data from the national database of hospitalizations from all patients who underwent cataract surgery alone or in combined procedures in Poland between January 2010 and December 2015 were assessed [11]. For each individual patient, cataract surgery alone or as a combined procedure with corneal transplantation, glaucoma filtration surgery, or vitrectomy was retrospectively identified. The ICD-9 code 13.4 was used to identify cataract extraction performed by phacoemulsification, with 13.2 , 13.3 and 13.5 codes used to identify other types of cataract extractions. The following NFZ codes were used: B12, B13, B14, B15, B18, and B19 with regard to cataract surgery alone; B04, B05, and B06 with regard to cataract surgery combined with corneal transplantations; B11 with regard to cataract surgery followed by glaucoma filtration surgery; B16 and B17 with regard to cataract surgery combined with vitrectomy." The ICD-10 codes H44.0 and H44.1 were used to identify endophthalmitis. All hospitalizations of patients who underwent cataract surgery alone or in combined procedures in Poland during the researched period, with a billing code of endophthalmitis, were selected. Acute endophthalmitis was diagnosed if the symptoms occurred between 1 - 42 days after cataract surgery and chronic endophthalmitis was diagnosed if the symptoms occurred ≥ 43 days after cataract surgery. Patients with diabetes mellitus were identified with ICD-10, E10 and E11 codes and received DM medication before cataract surgery. Population data were obtained from the Central Statistical Office of Poland (Główny Urząd Statystyczny- GUS) [12].

The statistical analysis included the annual volume of cataract surgery, calculations of incidence of both acute and chronic endophthalmitis , demographic and surgical characteristics of patients with endophthalmitis (the socio-demographic data including age, sex and place of residence were anonymously recorded). Independent Wald tests were used for risk factor analysis. Multiple logistic regression statistics were used to investigate the association of endophthalmitis with several risk factors, including age, gender, rural residence, one-day procedure, combined surgery, extracapsular cataract extraction surgical technique, surgery in anon-multidisciplinary hospital and presence of diabetes mellitus. Odds ratios (ORs) were computed. P values less than 0.05 were considered

statistically significant. The study protocol adhered to the tenets of the Declaration of Helsinki for research involving human subjects and was approved by the Polish Ministry of Health.

3. Results

Cataract surgery and post-operative endophthalmitis: Table 1 shows the number of all cataract surgeries performed in Poland alone or as combined procedures with vitrectomy, glaucoma filtration surgery and corneal transplantation, between January 2010 and December 2015, matched with population data by age group. In the researched period, the number of cataract surgeries in Poland increased by 17.9% from 201083 cases in year 2010 to 237098 cases in 2015, with a significant decrease in the years 2011-2013. In total, 1,218,777 cataract extractions (alone or combined with other procedures) were performed during 2010 -2015.

Table 1. Number of cataract surgeries performed in Poland from 2010 to 2015 matched with population data by age group.

Age 50-59 years No. of cataract surgeries	5770823 15598	5765460 13397	5656651 13203	5536118 13188	5406320 14645	5245352 14001
Age 60-69 years No. of cataract surgeries	3682048 38973	3931289 35322	4171206 37986	4409809 43120	4642821 52747	4888294 57646
Age ≥ 70 years No. of cataract Surgeries	4146056 141819	3852826 122035	3874727 126644	3889291 134212	3910358 156970	3932421 160905
In total No. of cataract surgeries	38517000 201083	38526000 175006	38534000 182005	38502000 194721	38484000 228864	38455000 237098
	2010	2011	2012	2013	2014	2015
Age 0-18 years No. of cataract surgeries	7643553 245	7630880 267	7531582 272	7431731 294	7367066 270	7309001 242
Age 19-39 years No. of cataract surgeries	12482309 1441	12523386 1305	12461398 1280	12355235 1324	12201430 1383	12015345 1384
Age 40-49 years No. of cataract surgeries	4792211 3007	4822159 2680	4838436 2620	4879816 2583	4956005 2849	5064587 2920

Among these cataract surgeries, 1331 were associated with post-operative endophthalmitis (POE), including 584 cases of acute POE (within 42 days from cataract surgery) and 747 chronic POE (≥ 42 days after cataract surgery) (Table 2). The overall incidence of POE decreased from 0.125% in 2010 to 0.066% in 2015 (with the mean incidence of 0.109%). The incidences of acute and chronic POE decreased from 0.047% and 0.078% in 2010 to 0.035% and 0.031% in 2015, respectively (Table 2).

Table 2. Incidence of acute and chronic post-operative endophthalmitis (POE) after cataract surgery in Poland from 2010 to 2015.

Year	No. of cataract surgeries	No. of cases of acute POE	Incidence of acute POE (%)	No. of cases of chronic POE	Incidence of chronic POE (%)	Total number of cases of POE	Total incidence of POE (%)
2010	201083	95	0.047%	157	0.078%	252	0.125%
2011	175006	95	0.054%	149	0.085%	244	0.139%
2012	182005	97	0.053%	124	0.068%	221	0.121%
2013	194721	118	0.061%	133	0.068%	251	0.129%
2014	228864	96	0.042%	110	0.048%	206	0.09%
2015	237098	83	0.035%	74	0.031%	157	0.066%
Total	1218777	584	0.048%	747	0.061%	1331	0.109%

The demographic and surgical characteristics of all cases of POE are presented in Table 3 and Table 4. The mean age of subjects with acute POE was 71.2 ± 11.9 years and of those with chronic POE it was 73.7 ± 12.1 years. In Poland, 28.85% of all cases of POE were identified in rural residents and 42.30% in men. Diabetes mellitus type 1 and type 2 were diagnosed in 4.43% and 18.78% of subjects with post-operative endophthalmitis, respectively. Extracapsular cataract extraction surgical technique was used in 5.94% of cases and 32.61% were identified after one-day cataract surgery. Post-operative endophthalmitis occurred in 137 eyes (10.30%) after cataract surgery combined with pars plana vitrectomy, in 20 eyes (1.50%) after cataract surgery combined with glaucoma filtration surgery and in 16 eyes (1.20%) after cataract surgery combined with corneal transplantation. A total of 62.51% of all eyes affected by POE in Poland during 2010-2015 received antibiotic treatment and 37.49% had vitrectomy treatment (with the rate of 44.86% among the cases of acute POE) (Figure 1).

Table 3. Demographic characteristics of all post-operative endophthalmitis (POE) cases after cataract surgery in Poland during 2010-2015.

	Acute POE (n, %)	Chronic POE (n, %)	Total number of cases of POE (n, %)
Age :			
0-18	0 (0.00%)	0 (0.00%)	0 (0.00%)
19-39	22 (3.77%)	13 (1.74%)	35 (2.63%)
40-49	16 (2.74%)	20 (2.68%)	36 (2.70%)
50-59	51 (8.73%)	66 (8.83%)	117 (8.79%)
60-69	125 (21.40%)	167 (22.36%)	292 (21.94%)
70+	370 (63.36%)	481 (64.39%)	851 (63.94%)
Sex:			
Women	328 (56.16%)	440 (58.90%)	768 (57.70%)
Men	256 (43.84%)	307 (41.10%)	563 (42.30%)
Urban residence Rural residence	408 (69.86%)	539 (72.15%)	947 (71.15%)
	176 (30.14%)	208 (27.85%)	384 (28.85%)
Diabetes mellitus E10	24 (4.11%)	35 (4.69%)	59 (4.43%)
Diabetes mellitus E11 No diabetes mellitus	99 (16.95%)	151 (20.21%)	250 (18.78%)
	461 (78.94%)	561 (75.10%)	1022 (76.79%)

Table 4. Surgical characteristics of all post-operative endophthalmitis (POE) cases after cataract surgery in Poland during 2010-2015.

	Acute POE (n,%)	Chronic POE (n,%)	Total number of cases of POE (n,%)
• Cataract surgery combined with glaucoma filtration surgery	71 (12.16%)	66 (8.84%)	137 (10.30%)
• Cataract surgery combined with pars plana vitrectomy			
• Non-combined cataract surgery	509 (87.16%)	649 (86.88%)	1158 (87.00%)
• Cataract surgery in a multidisciplinary hospital	559 (95.72%)	704 (94.24%)	1263 (94.89%)
• Cataract surgery in a non-multidisciplinary hospital	25 (4.28%)	43 (6.76%)	68 (5.11%)
Surgical technique of phacoemulsification	561 (96.06%)	691 (92.50%)	1252 (94.06%)
• extracapsular cataract extraction surgical technique	23 (3.94%)	56 (7.50%)	79 (5.94%)
• One-day cataract surgery	219 (37.50%)	215 (28.78%)	434 (32.61%)
• Cataract surgery other than one-day surgery	365 (62.50%)	532 (71.22%)	897 (67.39%)
• Cataract surgery combined with corneal transplantation	0 (0.00%)	16 (2.14%)	16 (1.20%)
	4 (0.68%)	16 (2.14%)	20 (1.50%)

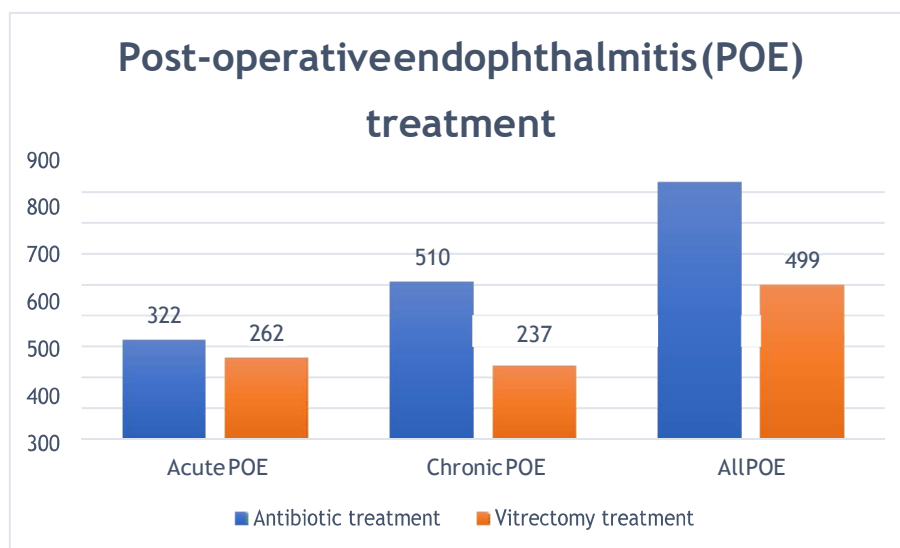


Figure 1. Treatment of post-operative endophthalmitis (POE) after cataract surgery in Poland during 2010-2015.

Multiple logistic regression modeling: Multivariate logistic regression models were constructed to analyze the risk factors for acute and chronic post-operative endophthalmitis (POE)

after cataract surgery in Poland during 2010-2015 (Table 5). The sensitivity/specificity evaluation of multiple logistic regression models for acute and chronic post-operative endophthalmitis with Receiver Operating Characteristic (ROC) curves are presented in Figure 2 and Figure 3. Our analysis showed that acute POE was significantly associated with age (OR 0.99, 95% CI 0.98-1.00) and male sex (OR 1.35, 95% CI 1.11 – 1.64). Chronic POE was also significantly associated with male sex (OR 1.28 , 95% CI 1.08-1.53) as well as with type II diabetes mellitus (OR 1.42, 95% CI 1.18 – 1.75), extracapsular cataract extraction (OR 3.09, 95% CI 2.20 – 4.23) and one-day surgery (OR 0.75, 95% CI 0.61 – 0.91). The combined cataract surgery was a significant risk factor for both acute and chronic POE (OR 4.25, 95% CI 3.09 – 5.74 and OR 4.41 , 95% CI 3.38 – 5.67), respectively. No association was found between acute and chronic POE with the surgery in a non-multidisciplinary hospital or with rural residence of our study subjects.

Table 5. Multiple logistic regression models of the risk factors for acute and chronic post-operative endophthalmitis (POE).

Variables	Acute POE	Chronic POE
	OR, 95% CI, p value	OR, 95% CI, p value
Age, per year increase	0.99 (0.98 – 1.00) p= 0.047	1.00 (0.99 – 1.01) p= 0.454
Men vs. women Rural residence	1.35 (1.11 – 1.64) p= 0.003	1.28 (1.08 – 1.53) p= 0.005
	1.22 (0.98 – 1.50) p= 0.069	0.98 (0.80 – 1.18) p= 0.811
Type II diabetes mellitus	1.18 (0.91 – 1.52) p= 0.198	1.42 (1.18 – 1.75) p= 0.001
Extracapsular extraction	1.40 (0.77 – 2.31) p= 0.226	3.09 (2.20 – 4.23) p= 0.000
One-day surgery	1.11 (0.90 – 1.36) p= 0.323	0.75 (0.61 – 0.91) p= 0.004
Combined cataract surgery	4.25 (3.09 – 5.74) p= 0.000	4.41 (3.38 – 5.67) p= 0.000
<u>Surgery in a non-multidisciplinary hospital</u>	0.77 (0.47 – 1.17) p= 0.246	0.87 (0.58 – 1.24) p= 0.474

OR= odds ratio, CI= confidence interval.

4. Discussion

Our study provides, for the first time, data concerning the incidence and characteristics of post-operative endophthalmitis (POE) after cataract surgery in the Eastern Europe. The study evaluates trends of acute and chronic POE after cataract surgery in the overall population of Poland in the years 2010 -2015. During the study period, the total number of all POE cases decreased from 252 in the year 2010 to 157 in the year 2015, while the total number of cataract surgeries increased from 201083 cases in the year 2010 to 237098 cases in 2015. The overall incidence of POE decreased from 0.125% in 2010 to 0.066% in 2015, with significant decrease in the incidences of both acute and chronic POE.

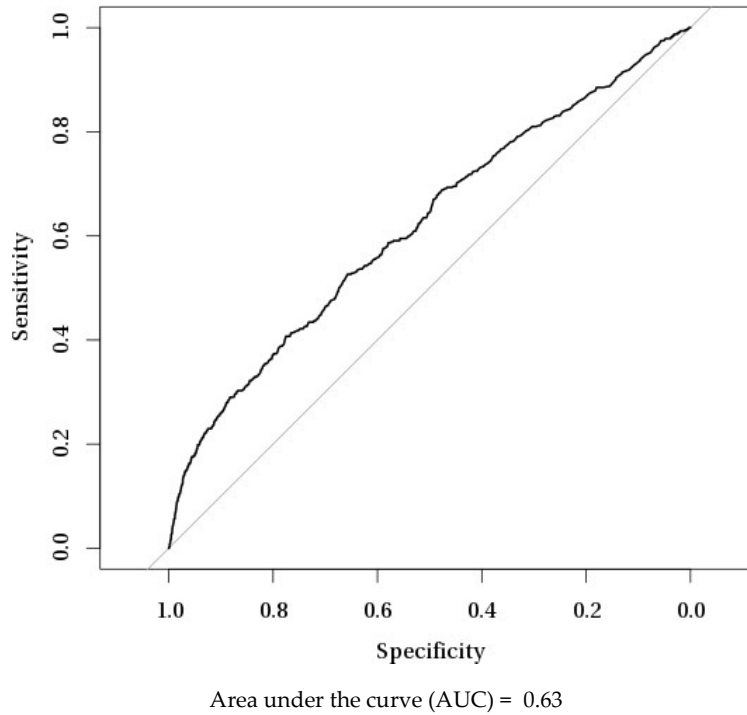


Figure 2. Receiver Operating Characteristic (ROC) curve analysis of sensitivity/specificity evaluation of multiple logistic regression model for acute post- operative endophthalmitis.

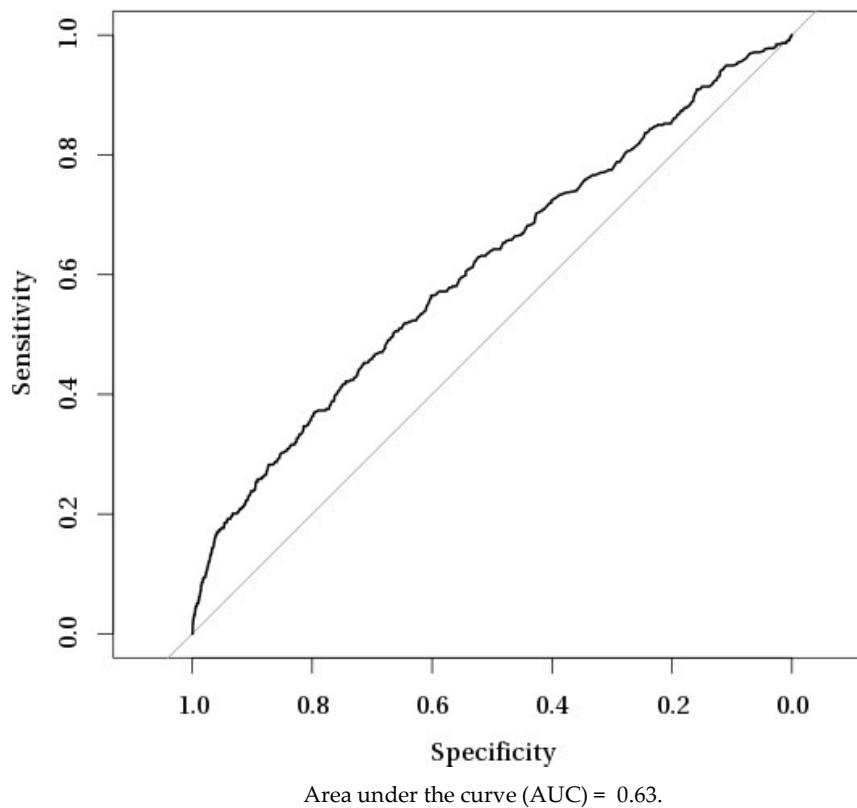


Figure 3. Receiver Operating Characteristic (ROC) curve analysis of sensitivity/specificity evaluation of multiple logistic regression model for chronic post- operative endophthalmitis.

Our findings are in agreement with the results of the recent studies from other countries, which showed a significant decrease in the incidence of POE after cataract surgery over time. [6,7,13,14,15] The results of the recent studies of POE which comprised over 100 000 participants are presented in Table 6. Our total incidence rate of POE (0.109%) was similar to the rate found in a nationwide study in France. [7] It was lower than the rates found in Canada and the Medicare Database in USA [8,9,13] and was higher than the rates found in Malaysia, Sweden and in members of Kaiser Permanente, California, USA [6,14,16]. But those studies recorded only the incidence of acute post-operative endophthalmitis after cataract surgery. Our total incidence rate of acute POE was rather low (0.048%) and was the second lowest among nationwide studies after the incidence rate in Sweden. In Poland, the recorded incidence rate of chronic POE in the years 2010-2015 (0.061%) was higher than that of acute POE. However, during the study period it has reversed and in the year 2015 the incidence of acute POE was higher than the incidence of chronic POE. Direct comparison of our results to the results obtained in studies from Iran and India [2,17] is limited due to the difference in study design. Although they comprised over 100.000 participants, those two studies were single-hospital studies. Between the years 2010 -2015, no simultaneous bilateral endophthalmitis was officially reported in Poland, since the legal regulations for immediate sequential bilateral cataract surgery (ISBCS) were introduced in January 2017. However, the results of recently published studies on ISBCS revealed that when the guidelines for strict separation of the two surgical procedures were followed, as well as after separate bilateral cataract surgeries less than 5 days apart, no simultaneous bilateral endophthalmitis was detected [18,19].

In our study, increasing age was significantly associated with acute POE, while type II diabetes mellitus, extracapsular cataract extraction and one-day surgery were significantly associated with chronic POE. The combined cataract surgery and male sex were significant risk factors for both acute and chronic POE. Our findings were in agreement with the results of some previous studies, which revealed that acute POE was significantly associated with older age, male gender, black race, diabetes mellitus, presence of renal disease as well as extracapsular cataract extraction, cataract surgery combined with other procedures, intraoperative posterior capsule rupture and non-use of intracameral antibiotic. [2,6,7,13,14,16,20,21]

Table 6. Comparison of the incidence rates of post-operative endophthalmitis (POE) from recent studies which comprised over 100 000 participants.

Epidemiological study	Total number of cataract extractions	Time period (years)	Total incidence of POE (number, %)	Incidence of acute POE † (number,%)	Incidence of chronic POE ‡ (number,%)	Incidence reduction from (%) to (%)
Nationwide Study in France (France) ⁷	6,371,242	2005-2014	6,668 (0.105%)	6,668 (0.105%)	NA	0.145%-0.053%
Medicare Database of Cataract Surgery (USA) ¹³	3,280,966	2003-2004	4,006 (0.122%)	4,006 (0.122%)	NA	0.132%-0.111%
National Database of Hospitalizations – current study from Poland	1,218,777	2010-2015	1331 (0.109%)	584 (0.048%)	747 (0.061%)	0.125%-0.066%
Quebec State Control for Health Insurance (Canada) ⁸	490,690	1996-2005	754 (0.154%)	754 § (0.154%)	NA	2.1%-0.8% β
Farabi Eye Hospital (Iran) ²	480,104	2006-2014	112 (0.023%)	100 (0.021%)	12 (0.002%)	NA

Swedish National Study (Sweden) ⁶	464,996	2005-2010	135 (0.029%)	135 (0.029%)	NA	0.03%-0.02%
Ontario Health Insurance Plan (Canada) ⁹	442,177	2002-2006	617 (0.139%)	617 Γ (0.139%)	NA	NA
Kaiser Permanente (USA) ¹⁶	315,246	2005-2012	215 (0.068%)	215 \S (0.068%)	NA	NA
The Malaysian cataract surgery registry (Malaysia) ¹⁴	163,503	2008-2014	131 (0.08%)	131 (0.08%)	NA	0.11%-0.08%
Aravind Eye Hospital (India) ¹⁷	116,714	2014-2015	65 (0.056%)	65 (0.065%)	NA	NA

† Acute endophthalmitis was identified if the symptoms occurred within 1 - 42 days from cataract surgery; ‡ Chronic endophthalmitis if the symptoms occurred \geq 43 days after cataract surgery; § Acute endophthalmitis was identified if the symptoms occurred within 1 - 90 days from cataract surgery; Γ Acute endophthalmitis was identified if the symptoms occurred within 1 - 14 days from cataract surgery; β Rate per 1000 cataract surgical procedures.

Although intracameral cefuroxime (Aprokam, Laboratoires Thea, Clermont- Ferrand, France) was commercially available in Poland since 2012, we did not include the intracameral antibiotic injection into the multiple regression analysis of endophthalmitis risk factors. This procedure was not widely used during the study period due to the significant reduction in the reimbursement cost of cataract surgery by the National Health Fund.

There are some limitations related to the present study. The major limitation is the possible presence of misclassification. The diagnosis of endophthalmitis was based on clinical presentation rather than a more strict bacteriological definition. Other limitations include errors in using specific ICD-10, ICD-9 and NFZ codes. However, such mistakes likely had only a minor impact on the study findings, because the present study was country-based and covered the overall population of Poland. During the study period, the use of intracameral antibiotic injection at the end of cataract surgery was not officially reported in the NFZ national database of hospitalizations. It needs a further evaluation as well as the cost-effectiveness of this prophylaxis to reduce the substantial costs associated with the treatment of POE after cataract surgery. [22]

5. Conclusions

In summary, our study showed, for the first time, the incidence of acute and chronic POE after cataract surgery in the overall population of Poland in the years 2010-2015 as well as the existing risk factors. During the study period, the total incidence of post-operative endophthalmitis after cataract surgery decreased significantly, while the total the number of cataract surgeries significantly increased. Globally, the large population-based data regarding the incidence rate of chronic POE are still lacking. The present study is the first nationwide study which reports the prevalence of chronic POE after cataract surgery.

Author Contributions: Michal S. Nowak and Andrzej Grzybowski conceived and designed the experiments. Data was collected by Milena Koziol and Wojciech Niemczyk. The results were analyzed by Michal S. Nowak, Andrzej Grzybowski, Iwona Grabska-Liberek, Katarzyna Michalska-Malecka and Jacek Szaflik. The first and final drafts were written by Michal Nowak. The defects of draft were critiqued by Andrzej Grzybowski and Iwona Grabska-Liberek. All authors agreed on the final draft of this study.

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Conflicts of Interest: The authors declare no conflict of interest.

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