

## ORIGINAL ARTICLES—Clinical science

## Risk of endophthalmitis after cataract extraction: results from the International Cataract Surgery Outcomes study

Jens Christian Norregaard, Henrik Thoning, Peter Bernth-Petersen, Tavs Folmer Andersen, Jonathan C Javitt, Gerard F Anderson

### Abstract

**Aim**—To estimate risk of infectious endophthalmitis after cataract extraction in Denmark and to compare results with the risk of this complication in the USA

**Methods**—In the national Danish administrative hospital register, 19 426 patients were identified who underwent first eye cataract surgery from 1985 to 1987 and who were 50 years of age or older. Of these, 61 patients had postoperative endophthalmitis.

**Results**—A 12 month cumulative risk of rehospitalisation for endophthalmitis was estimated at 0.18% (95% CI 0.09–0.26) after extracapsular cataract extraction with lens implant. Advanced age, male sex, intracapsular cataract extraction, and anterior vitrectomy were all associated independently with an increased risk of postoperative endophthalmitis. When restricting the sample to patients aged 65 years or older, in order to allow comparisons to be made with the US National Study of Cataract Outcomes, a 12 month risk of 0.17% (95% CI 0.08–0.25) was estimated. The previously reported US risk of 0.12% is included in the confidence interval of the risk estimated in the Danish sample.

**Conclusion**—Despite considerable differences in the healthcare systems, no statistically significant difference in outcome of surgery as measured by risk of endophthalmitis was shown between Denmark and the USA.

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Infectious endophthalmitis after cataract extraction is a rare but serious complication, which threatens the visual outcome of cataract surgery. A few studies reporting endophthalmitis after extracapsular cataract extraction (ECCE) have been published. The risks of endophthalmitis reported from these studies are 0.38%,<sup>1</sup> 0.22%,<sup>2</sup> and 0.3%.<sup>3,4</sup> In the US

National Study of Cataract Outcomes, a 12 month risk of 0.12% was observed following extractions performed in hospitals<sup>5</sup> and 0.08% following outpatient procedures.<sup>6</sup> As in the present study, these results were based on clinically diagnosed cases of endophthalmitis. If only culture proved cases of endophthalmitis are included, an incidence as low as 0.07% has been reported.<sup>7</sup>

It is difficult to provide a precise estimate of the occurrence of endophthalmitis, since a very large sample size is required for this rare complication. The most recently published large studies are based on data from study populations in the USA.<sup>2,5-7</sup> It is currently unknown whether these results may be generalised to other healthcare systems. Many studies of endophthalmitis after cataract surgery are based on patients treated by individual surgeons or at academic centres.<sup>1,2,7</sup> Such series do not necessarily reflect the rate of complications in the entire healthcare system and they may not be adequate for generalisation, even within the same healthcare system. In this study, we have used a nationwide administrative database, as this can provide a large and total national sample of cataract patients.

As a cross national comparison can be a powerful method when assessing wider applicability of clinical results, this Danish study was designed and carried out in close collaboration with the US National Study of Cataract Outcomes.<sup>5</sup> We kept definitions of events and methods of data analysis in the present Danish study similar to those used in the US study, in order to maximise the comparability of results. It is, therefore, possible for us to subsequently compare Danish results with those previously reported from the US National Study.<sup>5</sup>

The present study is part of the International Cataract Surgery Outcomes Study sponsored by the Agency for Health Care Policy and Research (USA). This project consists of a series of studies examining and comparing outcomes of cataract surgery in different health care settings.

Department of Social Medicine, Faculty of Health Science, University of Copenhagen, Denmark  
J C Norregaard  
T F Andersen

Danish Institute for Clinical Epidemiology, Copenhagen, Denmark  
H Thoning

Department of Ophthalmology, Hvidovre University Hospital, Copenhagen, Denmark  
J C Norregaard  
P Bernth-Petersen

Worthen Center for Eye Care Research, Georgetown University, Washington DC, USA  
J C Javitt

Department of Health Policy and Management, Johns Hopkins University, Baltimore MD, USA  
G F Anderson

Correspondence to:  
Jens Christian Norregaard, MD, Department of Social Medicine, University of Copenhagen, Blegdamsvej 3, 2200 Copenhagen N, Denmark.

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## Material and methods

### DANISH SAMPLE OF CATARACT PATIENTS

We performed a retrospective cohort study based on the Danish National Patient Register (DNPR), which is a nationwide register covering all hospital admissions in Denmark. For each admission to a public health service hospital, a discharge summary is drawn up reporting diagnoses and surgical procedures performed during the admission. The corresponding International Classification of Diseases codes for diagnoses and surgical procedures<sup>8</sup> are routinely reported to the DNPR. Every Danish citizen has been assigned a personal identification number, which is used by public authorities including the DNPR. Using this number as a key to linkage, it is possible to identify, obtain, and aggregate longitudinal, person specific information from various public registers.

The register is the only possible source of nationwide data. The register includes information on inpatient activities only. As the fraction of outpatient cataract surgery has increased rapidly since 1987,<sup>9</sup> we decided to study patients who underwent cataract surgery between 1985 and 1987, in order to avoid a potential selection bias. Both extracapsular cataract extraction (ECCE) and intracapsular cataract extractions (ICCE) were studied. In the analyses, most attention, however, has been given to the current ECCE technique with intraocular lens (IOL) implantation.

We identified all patients 50 years of age or older who underwent cataract extraction on an inpatient basis between 1985 and 1987. Any admission with a code for cataract extraction reported to the register was identified. We denoted the admission during which a cataract extraction was performed as the *index admission*. If two cataract extractions were identified for a single patient during the study period, the first occurrence was chosen as the index admission. We excluded 111 cases of cataract surgery combined with other ocular procedures such as corneal graft, glaucoma, or posterior segment procedures. In addition, eight cases were excluded after a review of medical records as described in detail below. Including patients with anterior vitrectomy during index surgery, we finally identified and followed 19 426 cataract patients. In the comparable US National Study, 325 324 Medicare beneficiaries operated on in 1984 were studied.

All other admissions experienced by the cataract patients between index admission and 1 January 1992 were identified in the DNPR. In this way, a complete history of admissions was created for all patients from their index surgery and continuing 4 to 7 years beyond. Since the exact date of surgery is not available in the register, the date of the index admission was used instead. Patients were followed until any of the following events occurred: an episode of endophthalmitis, any other intraocular procedure, death, or end of study period. An episode of endophthalmitis was assumed to occur if an admission with a diagnosis of endophthalmitis was identified. Date of death was obtained by linking all

patients to the Central Danish Person Register using the person identification number.

### COMPARABILITY BETWEEN THE US AND THE DANISH STUDY

In order to obtain Danish results which could subsequently be compared with those of the US National Study of Cataract Outcomes, definition of events and design of data analysis were developed to emulate the US study as closely as possible. The US study is described in detail elsewhere.<sup>5</sup> In summary, it was based on 325 324 Medicare beneficiaries operated on in 1984 with a minimum follow up of 3 years. Data were obtained from the Medical Provider Analysis and Review (MEDPAR) file maintained by the Health Care Financing Administration (HCFA). During the study period, ICD9 codes were used in US medical files. Consequently, codes used for definition of events in the US study had to be translated by the Danish team into corresponding Danish ICD8 codes. Problems of classification were clarified through personal communication with members of the US team. Exclusion of patients owing to combined procedures during index admission is consistent with the US study design.

### QUALITY OF DATA

In order to evaluate the *completeness* of the reporting of cataract extraction to the DNPR, we compared the number of cataract extractions identified in the DNPR with other data sources. In 1987, the Danish Ophthalmological Society carried out a national survey obtaining information through personal contact with all ophthalmic departments performing surgery.<sup>10</sup> A difference of 4.2% in the number of extractions was observed between this survey and the DNPR data. For one hospital (Hvidovre University Hospital), we also examined the local surgical records of the department. For 1986, a difference in numbers was observed at 0.6% between the two data sources.

We also examined the *validity* of the DNPR data regarding endophthalmitis. The medical records of all cases with a code indicating post-operative endophthalmitis were requested from the clinics involved. Incorrect data were observed in the DNPR for eight cases, which were therefore excluded. In two of these cases index surgery was a combined procedure including corneal grafting, and for the other six cases the code for endophthalmitis had been applied incorrectly to the index admission. Seven medical records could not be found, because the clinics had been closed or because the whereabouts of the records were unknown. We decided not to exclude these cases.

### STATISTICAL METHODS

Kaplan–Meier life tables were used for calculating cumulative risk of endophthalmitis. Subgroups were compared by the log rank test.<sup>11</sup> The relative importance of age, sex, and type of surgery as prognostic indicators was evaluated using the exact logistic regression method.<sup>12</sup> A 5% level of significance was used and 95%

**Table 1** Demographic and clinical characteristics, and cases of endophthalmitis within 4 years after surgery among 19 426 Danish cataract surgery patients (aged 50 years or older)

	No of patients (% of total sample)	Cases (% of strata)
Total	19 426 (100)	61 (0.31)
Type of surgery:		
ICCE – IOL	2 639 (13.6)	14 (0.53)
ICCE + IOL	4 572 (23.5)	17 (0.37)
ECCE – IOL	1 443 (7.4)	9 (0.62)
ECCE + IOL	10 559 (54.4)	19 (0.18)
Extraction (any type) with anterior vitrectomy	213 (1.1)	2 (0.94)
Sex:		
Female	12 592 (64.8)	31 (0.25)
Male	6 834 (35.2)	30 (0.44)
Age (years):		
50–59	1 198 (6.2)	3 (0.25)
60–69	3 554 (18.3)	9 (0.25)
70–79	7 959 (41.0)	25 (0.31)
80–89	6 041 (31.0)	17 (0.28)
≥90	674 (3.5)	8 (1.19)

ECCE=extracapsular cataract extraction; ICCE=intracapsular cataract extraction; IOL=intraocular lens.

**Table 2** Cumulative risk of endophthalmitis among 19 426 Danish cataract surgery patients (aged 50 years or older)

	Cumulative 1 month risk (95% CI)	Cumulative 12 month risk (95% CI)
ICCE – IOL	0.31% (0.09–0.52)	0.52% (0.24–0.80)
ICCE + IOL	0.35% (0.18–0.53)	0.38% (0.20–0.56)
ECCE – IOL	0.42% (0.08–0.76)	0.50% (0.13–0.87)
ECCE + IOL	0.15% (0.08–0.23)	0.18% (0.09–0.26)

Log rank test 12 month:  $p=0.002$ .

confidence intervals (CI) were calculated when appropriate. SAS version 6.09 was used for survival analysis and LOGXACT ver 1.1, Cytel 1993, for exact logistic regression.

The study was approved by the medical ethics committee for Copenhagen, Denmark.

## Results

Demographic and basic clinical information of the Danish sample are shown in Table 1. In all, 61 cases were identified and of these 47 (77%) occurred within the first months after surgery. Cumulative 1 month and 12 month risks of endophthalmitis were calculated for four different types of routine cataract surgery (Table 2). In accordance with the US study, patients with combined surgery and anterior vitrectomy during index surgery were excluded from this analysis. The highest 12 month risk was seen for ICCE without IOL (0.52%), followed by ECCE without IOL (0.50%), ICCE with anterior chamber IOL (0.38%), and ECCE with IOL (0.18%). In pairwise

**Table 3** Determinants of risk of endophthalmitis among 19 426 Danish cataract surgery patients estimated by exact logistic regression

Variable	Odds ratio (95% CI)	p Value
Age (years):		
50–89	1.00	ref
≥90	3.62 (1.53–8.56)	0.003
Sex:		
Female	1.00	ref
Male	1.93 (1.07–3.50)	0.028
Type of surgery:		
ECCE with IOL	1.00	ref
ICCE	2.22 (1.22–4.17)	0.007
Anterior vitrectomy:		
Not performed	1.00	ref
Performed	4.86 (1.17–20.27)	0.030

comparisons, the 12 month risk in the ECCE with IOL subgroup was significantly lower than the risk in any other subgroup ( $p < 0.018$ ).

As ECCE with IOL is currently the standard treatment modality, further analyses were done for this subgroup. If cases with anterior vitrectomy during index surgery were included, the 12 month cumulative risk increased from 0.18% to 0.19% (95% CI 0.11–0.28). Only one case of endophthalmitis following ECCE with IOL (5.0%) was seen more than 12 months after index surgery. This last case appeared in the fourth year after index surgery. The 4 year cumulative risk was 0.20% (95% CI 0.11–0.28). No significant differences were seen within the ECCE with IOL subgroup according to sex and age in univariate analyses.

To evaluate the relative importance of age, sex, and type of surgery we used an exact logistic regression model with occurrence of endophthalmitis within the first 12 months after surgery as the dependent variable. In this analysis, cases with anterior vitrectomy during index surgery were included. In the model, the ECCE technique with IOL was compared with ICCE regardless of implantation (Table 3). Significantly higher odds were seen for male patients than for females, when controlling for all other variables. Also, for patients ≥90 years old compared with the other age groups, a higher odds was observed. No significant difference between the other 10 year age groups was seen in interim analyses. Significantly higher odds were seen for ICCE and for cases with anterior vitrectomy during index surgery. No significant interaction between any of the variables was observed.

## COMPARISON OF THE DANISH RESULTS WITH THE US NATIONAL STUDY OF CATARACT OUTCOME

In the US national study, only patients aged 65 years or older could be included. Table 4 shows a comparison of the US sample and the Danish subsample of patients aged 65 years or older. The DNPR has no data on race, but approximately 99% of the studied age group were white compared with 90% in the US study. The proportion of males was minimally higher in the Danish sample (33.2% *v* 31.7%). More intracapsular cataract extractions were performed in Denmark during the study period than in the US (38.5% *v* 30.7%). The mean age for Danish patients aged 65 years and older was 77.6 years compared with 76.6 years in the US sample.

In the US study, no distinction between extraction with or without IOL was made and cases with anterior vitrectomy were excluded. For the ECCE group, a US 12 month cumulative risk of endophthalmitis of 0.12% was estimated. In the Danish subsample of patients aged 65 years or older, a 12 month cumulative risk of 0.17 (95% CI 0.08–0.25) was observed following ECCE with IOL.

## Discussion

The present study was based on a nationwide database, in which the total national caseload of cataract surgery was identified. The advan-

Table 4 Clinical characteristics of 16 752 Danish cataract surgery patients (65 years of age or older) compared with 325 324 patients from a similar US study<sup>†</sup>

	Denmark (1985–7)		USA (1984)	
	No of patients (% of total sample)	No with endophthalmitis (% of strata)	No of patients (% of total sample)	No with endophthalmitis (% of strata)
Total	16 752 (100)	52 (0.31)	325 324 (100)	440 (0.13)
Type of surgery:				
ICCE – IOL	2 223 (13.3)	12 (0.54)		
ICCE + IOL	4 215 (25.2)	16 (0.38)	99 971 (30.7)	170 (0.17)
ECCE – IOL	1 125 (6.7)	8 (0.71)		
ECCE + IOL	9 189 (54.8)	16 (0.17)	225 353 (69.3)	270 (0.12)
Sex:				
Male	5 570 (33.2)	25 (0.45)	103 140 (31.7)	161 (0.16)
Female	11 182 (66.8)		222 184 (68.3)	279 (0.12)
Age (years):				
65–69	2 232 (13.3)	5 (0.22)	56 050 (17.2)	83 (0.15)
70–79	7 873 (47.0)	23 (0.29)	159 476 (49.1)	211 (0.13)
80–89	5 977 (35.7)	16 (0.27)	98 590 (30.3)	128 (0.13)
≥90	670 (4.0)	8 (1.19)	11 208 (3.4)	18 (0.16)

tages of this strategy are obvious. It provides a large sample size necessary for reliable estimation of risks of rare complications. It also has the advantage of providing results applicable to the entire healthcare system, and thus provides evidence of the effectiveness of current practice. By assuring uniformity in the definitions of events and in the design of analyses, it has been possible to conduct a valid comparison of this particular adverse outcome of cataract extraction between the surgery performed in the USA and in the public Danish healthcare system. Similar cumulative risks of endophthalmitis were shown, as the US cumulative 12 month risk of 0.12% for ECCE is close to and included in the confidence interval of the Danish risk of 0.17%. Thus, despite differences in the organisation and management of cataract surgery in the public Danish healthcare system and the private US system, this study demonstrates comparable quality of care regarding this severe complication.

The examined risk factors were all significantly associated with the risk of endophthalmitis. The association with age and sex has not previously been reported. The increased risk with age was only true for the very old ages (≥90 years) and this result might be explained by a reduced natural immunity in this advanced age group. The association with capsular rupture and anterior vitrectomy during index surgery has previously been observed.<sup>2 5 13</sup> This is in accordance with the belief that the elimination of bacteria from the vitreous cavity is much less efficient when compared with the anterior chamber.<sup>14</sup>

The proportion of cataract extractions performed in outpatient settings or in private clinics increased rapidly after 1987 and this activity was not reported to the DNPR. As only about 5% of the cataract surgery performed in Denmark between 1985 and 1987 was carried out on an outpatient basis or in private clinics,<sup>9</sup> we decided to use data from the period 1985 to 1987 to minimise selection bias. We believe that the results are still valid today as the effectiveness of the ECCE technique is unlikely to have changed markedly since then. When comparing the information obtained from the DNPR with other available data sources

including medical charts, the validity of the data appears to be good. We were able to review most medical records of cases of endophthalmitis and subsequently to correct any error in the database. A previous Danish study from 1975 of 4498 ICCE without IOL showed an incidence of 0.53%.<sup>15</sup> This result is very similar to the 12 month risk of 0.52% observed in the present series and supports the reliability of the present data. Detection of a case of endophthalmitis required that the case had been treated in a public hospital. However, no cases of endophthalmitis would have been treated on an outpatient basis or in a private clinic in Denmark during that period. The nationwide status of the DNPR leaves no further losses to follow up except emigration, which is very rare in the studied age groups.

A comparison of US and Danish results relies on assumptions of comparability in definitions of events and design of the analysis. Great care was taken in the translation of codes, but some differences could not be avoided. During the study period, phacoemulsification was not coded separately in the DNPR, but was categorised as ECCE. We know that very few, if any, phacoemulsification procedures were performed in Denmark at that time and, therefore, the two ECCE samples still appear to be comparable. The US ECCE sample includes patients who had an ECCE without IOL. In another US study of Medicare beneficiaries in 1986, it was observed that only 2% of the ECCE procedures were performed without IOL.<sup>16</sup> This indicates that, in the present study, it is appropriate to compare the US ECCE subgroup with the Danish ECCE with IOL subgroup.

Quite obviously quality assessments and studies of effectiveness need to be undertaken in individual healthcare systems all over the world. However, it is possible to significantly improve the level of information and assurance through international comparative studies. The current study is thus, first of all, able to document the state of affairs regarding risk of endophthalmitis. This is an important aspect of quality in Danish cataract management, but at the same time the study provides an opportunity to make comparisons between the

quality of care as it is provided in the private US and public Danish healthcare systems. Once demonstrated, the similar clinical results obtained in a different healthcare system, do improve the level of confidence in a clinical standard against which the quality of care can be evaluated.

Lists of all codes for diagnosis and procedures available from authors on request.

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