

Immediate sequential bilateral cataract surgery: a 13-year real-life report of 56 700 cataract operations

Pekko Hujanen (1,2), Anu Vaajanen, ^{1,2} Tuukka Felin, ^{1,2} Eemil Lehtonen, ^{1,2} Ulla Syvänen, ¹ Heini Huhtala (1), ³ Mika Helminen, ^{3,4} Harri Sintonen, ⁵ Anja Tuulonen, ¹ Hannele Uusitalo-Järvinen (1), ^{1,2}

ABSTRACT

Background/aims To assess the frequency of immediate sequential bilateral cataract surgery (ISBCS) and endophthalmitis during 13-year period in Tays Eye Centre, Tampere University Hospital, Tampere, Finland. **Methods** All cataract surgeries performed between

1 January 2008 and 31 December 2020, and all endophthalmitis cases during the same period were searched from electronic patient records. Numbers and frequencies of ISBCS, and complications, including endophthalmitis and vitreous loss, were recorded and compared with unilateral operations.

Results The study included 56 700 cataract surgeries in 34 797 patients of whom 39% (n=13 445) had ISBCS. The median age of the patients was 75 (IQR 68–80, range 0.08–99) years at the time of surgery. The proportion of ISBCS patients increased from 4.2% in 2008 to 46% in 2020. Vitreous loss occurred in 480 (0.9%) of cataract surgeries. There were no postoperative endophthalmitis after cataract surgery (n=0) during the 13-year period.

Conclusion The proportion of patients undergoing ISBCS increased from 4.2% in 2008 to 46% in 2020. No endophthalmitis were found to be associated with ISBCS.

INTRODUCTION

Cataract surgery is among the most frequently performed elective surgical procedures across the world. Due to development of modern surgical techniques, it has evolved into a safe operation, including adoption of same-day bilateral operations, immediate sequential bilateral cataract surgery (ISBCS). ISBCS provides benefits for patients and healthcare providers compared with delayed sequential bilateral cataract surgery (DSBCS).¹ Patients will have less hospital visits, less travelling and expenses, no waiting time for the second-eye surgery and less postoperative anisometropia.² Healthcare providers can offer faster access to surgery, more efficient use of operating capacity and clinic time, and reduced surgery-related costs.¹³ In spite of these benefits of ISBCS, concerns have also been raised especially for the fear of postoperative complications.

The most dreaded complication of cataract surgery is postoperative endophthalmitis with potential permanent loss of vision. The European Society of Cataract and Refractive Surgeons study is the only randomised controlled trial (RCT), which has tested endophthalmitis prophylaxis for cataract surgery.⁴ This pivotal trial demonstrated

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Immediate sequential bilateral cataract surgery (ISBCS) has recently gained increasing interest due to COVID-19 pandemic in order to halve the number of visits for surgery. This study is one of the largest to report experiences on ISBCS in real-life clinical practice.

WHAT THIS STUDY ADDS

⇒ No cases of endophthalmitis were found in this single-centre 13-year real-life study including all 56 700 cataract operations in 34 797 patients. ISBCS gradually increased from 4% in 2008 to 46% in 2020.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ ISBCS is an effective option to reduce the number of visits for patients and to improve access to surgery.

that the use of intracameral cefuroxime at the end of cataract surgery resulted in an almost fivefold decrease in the rate of endophthalmitis.⁴ In addition to cefuroxime, moxifloxacin and vancomycin are commonly used intracameral antibiotics both of which have demonstrated reduced prevalence of endophthalmitis compared with no antibiotic administration in several retrospective studies.⁵ However, not only endophthalmitis but also prevention of endophthalmitis may also lead to rare serious vision threatening adverse events. There are no published RCTs of different intracameral antibiotics to compare efficacy and safety, and no consensus on the optimal antibiotics to prevent postoperative endophthalmitis.⁶ Thus, it is important to evaluate real-world outcomes.

In the present study, we report outcomes of 56 700 consecutive cataract surgeries including 26 890 ISBCS eyes (47%).

METHODS

This is a single-centre report based on complete data collection on all cataract surgeries performed between 1 January 2008 and 31 December 2020 in Tays Eye Centre, Tampere University Hospital, Finland. Tampere University Hospital provides university-level services to 0.9 million Finns within three hospital districts. In addition, Tays Eye Centre is responsible for organising all public near

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¹Tays Eye Centre, Tampere University Hospital, Tampere, Finland ²Faculty of Medicine and Health Technology, Tampere University, Tampere, Finland ³Faculty of Social Sciences, Tampere University, Tampere, Finland ⁴Tays Research Services, Tampere, Finland ⁵Department of Public Health, University of Helsinki, Helsinki, Finland

Correspondence to

Dr Hannele Uusitalo-Järvinen, Tampere University Hospital, Tampere, 33520, Finland; hannele.uusitalo-jarvinen@ pshp.fi

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To cite: Hujanen P, Vaajanen A, Felin T, et al. Br J Ophthalmol Epub ahead of print: [please include Day Month Year]. doi:10.1136/ bjophthalmol-2021-320588 eye care services for 0.5 million inhabitants living in Pirkanmaa Hospital District, which is a joint municipal authority owned by 23 municipalities. In addition to patient care, Tays Eye Centre provides education and training for ophthalmology residents as well as academic research.

All patients who had undergone cataract surgery during the study period were searched from the electronic patient records (EPR) of Tampere University Hospital. The EPR was searched for all Nordic Classification of Surgical Procedures (NCSP) codes for cataract surgery and laterality of surgery (online supplemental table 1), the dates of cataract surgery codes and corresponding patient identification numbers. NCSP codes and dates for vitrectomy procedures and ICD10 codes for endophthalmitis were searched (online supplemental table 1) for patients who had undergone cataract surgery. In addition, ICD10 codes for endophthalmitis were searched from EPR, and the patient records were manually double checked to ensure that no postcataract surgery endophthalmitis cases were missed. Postoperative endophthalmitis or presumed endophthalmitis was defined by clinical diagnosis with a positive or negative culture of vitreous or aqueous sample, and treatment with intravitreal antibiotics within 30 days after cataract surgery.

The patient records for ISBCS cases with operation code for vitrectomy were also screened to evaluate whether the vitrectomy code applied to the first or the second eye operated. The number of cataract surgeries and anterior vitrectomies performed by specialist surgeons and residents as well as number of planned phacovitrectomies were collected from Centricity Opera software (GE Healthcare, UK), which is used in operating theatre administration.

To evaluate number of cataract surgeries per 1000 inhabitants and per 1000 inhabitants \geq 65 years old, the number of citizens living in Pirkanmaa Hospital District was collected and stratified by age using Statistics Finland's database (stat.fi/til/index_ en.html).

The regimen for routine phacoemulsification included sponging the periocular skin with 80% ethanol wipes, intraoperative surface irrigation with 5% povidone-iodine for 2 min, intracameral vancomycin (1 mg/0.1 mL) at the end of surgery and topical postoperative steroid-chloramphenicol eye drops for 3–4 weeks. In addition, until 31 December 2012 steroidchloramphenicol eye drops were instilled preoperatively after which this policy was abandoned in routine cataract surgery.

ISBCS were performed one eye at a time as two separate independent procedures. This included changing of sterile covering, gloves and gowns, irrigating solutions, all surgical instruments and packs between the operated eyes. However, neither different sterilisation cycles for instrument trays nor different lot numbers for disposable instruments, viscoelastics, antibiotics nor other pharmaceutical products were routinely used for each eye in ISBCS. The decision to offer ISBCS for the patient was based on individual surgeon's discretion and experience. ISBCS was always performed at the sole discretion of the patient and the surgeon. In general, ISBCS was not to be performed in cases with increased risk of infection (such as chronic blepharitis), corneal decompensation (endothelial dystrophy or guttata), inaccurate biometry (previous refractive surgery), lenticular abnormalities (phacodonesis, history of ocular trauma) or advanced glaucoma, uveitis or other uncontrolled/untreated ocular comorbidity with potential for postoperative worsening. In addition, ISBCS was not performed in cases of challenges or complications during the first eye surgery or in cases where the patient preferred to have one eye at the time operated. Pseudoexfoliation, intraoperative floppy iris syndrome, previous or ongoing antivascular

endothelial growth factor treatment for retinal diseases were not generally considered as contraindication for ISBCS.

In the preplanned combined phacovitrectomy (all unilateral) procedures prophylactic measures included 3-day preoperative topical steroid-chloramphenicol eye drops, intraoperative surface irrigation with 5% povidone-iodine for 2 min, vancomycin (1 mg/100 mL) in the irrigating solution and postoperative topical steroid-chloramphenicol eye drops for 4 weeks. In addition to vancomycin in irrigating solution, no intracameral antibiotics were administered. The prophylactic measures in paediatric cataract operation were similar to phacovitrectomy. In young children, posterior capsulotomy and anterior vitrectomy were performed via pars plana at the time of cataract surgery, if neodymium:yttrium aluminium garnet capsulotomy was thought unlikely to be achieved after cataract surgery. In paediatric bilateral cataract cases, DSBCS was preferred over ISBCS. However, risks of bilateral intraoperative or postoperative complications were always weighed against the benefit or surgery under a single general anaesthesia, faster visual rehabilitation and lower risk of deprivation amblyopia. The decision was made based on the surgeon's discretion and experience.

The annual frequency of ISBCS and the rates of endophthalmitis in procedures performed with and without preoperative topical antibiotic eye drops were evaluated. In addition, patients' age and gender, number of cataract surgery procedures performed by residents, rates of anterior vitrectomies and implantation of anterior chamber intraocular lens (IOL), and planned phacovitrectomy procedures were determined.

All statistical analyses were performed with the SPSS (IBM Corp. Released 2013 and 2017. IBM SPSS Statistics for Windows). Between-group differences in the distributions of continuous variables were compared using the Mann-Whitney U test. A p value of 0.05 or lesser was considered statistically significant.

RESULTS

There were a total of 56 700 cataract surgeries in 34 797 patients (table 1). Overall, 10206 (18%) of cataract surgeries were performed by residents. The median age of patients remained between 74 and 76 years throughout the 13-year study period. The youngest operated patient was 1 month old and the oldest 99 years old. A vast majority of operated patient (29 151, 84%) were ≥ 65 years old.

A majority of cataract surgeries were performed under the operation code CJE20 (n=56700; 99%), which is used for routine

Table 1Demograpics and clinical characteristics for immediatesequential bilateral cataract surgery (ISBCS) and one eye at timecataract surgeries in Tampere University Hospital Eye Centre, 2008–2020

	All cataract surgeries	ISBCS	One eye at a time cataract surgeries
Eyes, n (%)	56 700 (100%)	26 890 (47%)	29 810 (53%)
Patients	34 797 (100%)	13 445 (39%)	21 352 (61%)
Age (years), median (IQR)	75 (68–80)	76 (70–81)	74 (67–80)
0–17 years	63 (0.2%)	8 (0.1%)	55 (0.3%)
18–44 years	427 (1.2%)	84 (0.6%)	343 (1.6%)
45–64 years	5156 (15%)	1526 (11%)	3630 (17%)
65–84 years	25 400 (73%)	10 324 (77%)	15 076 (71%)
>=85 years	3 751 (11%)	1 503 (11%)	2 248 (11%)
Female sex, n (%)	2 1026 (60%)	8 423 (63%)	12 603 (59%)

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Table 2	Cataracts surgery procedures performed in Tampere
University	Hospital Eye Centre, 2008–2020.

onversity hospital Lyc centre, 2000-2020.						
	2008–2	020	2008–2	2012*	2013–2	2020†
Cataract surgery procedures, n (%)	56 700	(100%)	14 435	(25%)	42 265	(75%)
CJE20, n (%)	56 295	(99%)	14 289	(99%)	42 006	(99%)
CJE15, n (%)	176	(0.3%)	58	(0.4%)	118	(0.3%)
CJD15, n (%)	34	(0.1%)	13	(0.1%)	21	(0.05%)
CJC15, n (%)	40	(0.1%)	25	(0.2%)	15	(0.04%)
CJD20, n (%)	16	(0.03%)	3	(0.02%)	13	(0.03%)
CJD30, n (%)	26	(0.05%)	3	(0.02%)	23	(0.05%)
CJE99, n (%)	70	(0.1%)	22	(0.2%)	48	(0.1%)
CJD99, n (%)	28	(0.05%)	12	(0.08%)	16	(0.04%)
CJC99, n (%)	11	(0.02%)	9	(0.06%)	2	(0.005%)
CJD40, n (%)	4	(0.007%)	1	(0.007%)	3	(0.007%)

*Preoperative antibiotic eye drops were included in prophylaxis regimen until 31 December 2012.

tNo preoperative antibiotic eye drops were included in prophylaxis regimen since 1 January 2013.

CJC15, intracapsular cataract extraction with implantation of artificial lens in anterior chamber and iridectomy or iridotomy; CJC99, other intracapsular cataract operation; CJD15, extracapsular cataract extraction with implantation of artificial lens in anterior chamber and iridectomy or iridotomy; CJD20, extracapsular cataract extraction with implantation of artificial lens in posterior chamber; CJD30, pars plana lensectomy; CJD40, extracapsular cataract extraction with implantation of scleral fixed artificial lens in posterior chamber; CJD39, other extracapsular cataract operations; CJE15, phakoemulsification with implantation of artificial lens in anterior chamber and iridectomy or iridotomy; CJE20, phakoemulsification with implantation of artificial lens in posterior chamber; CJE9, other extracapsular cataract operation using phakoemulsification technique.

cataract surgery (table 2). CJE20 was used as the only operation code in 54 140 (95%) of surgeries. Overall, 1517 (2.7%) cataract surgeries were preplanned as combined phacovitrectomies. Remaining 1043 (2.3%) cataract surgeries were combined with other ophthalmic procedures such as intravitreal injection, trabeculectomy or Descemet stripping automated endothelial keratoplasty. The number and frequency of preplanned phacovitrectomies increased annually from 23 (0.8%) in 2008 to 249 (3.3%) in 2020.

Altogether, 13 445 (39%) patients had the ISBCS (26 649 (47%) of 56 700 operated eyes). The proportion of patients with ISBCS increased annually from 115 (4%) in 2008 to 1711 (46%) in 2020 (table 3). The median age of the ISBCS patients was slightly higher than those undergoing cataracts surgery one eye at a time (76 years, IQR 70–81 vs 74 years, IQR 67–80).

There were 480 cases of vitreous loss occurring during cataracts surgeries excluding planned phacovitrecotmy (n=1517) and paediatric cataract surgery (n=84) procedures. The incidence of vitreous loss during cataract surgery was 0.9% (480 cases in 55 099 surgeries). Overall, 122 (25%) of these occurred in cataract surgeries performed by residents. The frequency of anterior vitrectomy was higher in surgeries performed by residents compared with surgeries performed by specialist (1.54% vs 0.77%; p value is <0.00001, χ^2). All anterior vitrectomies in the ISBCS (n=70) took place in the second eye operated. Anterior chamber IOL was placed in 176 (0.3%) cases.

There were 84 paediatric cataracts surgeries performed in 63 patients under 18 years of age. Of these, surgery was performed in younger than 1 year old 13 children's 20 eyes, in 2 children's 3 eyes between 1 to <2 years of age, in 35 eyes of 28 children between ages of 2 to <13 years and in 26 eyes of 20 children between ages of 13 to <18 years. There were 42 children

Table 3Number and frequency of same-day bilateral cataractsurgeries Tampere University Hospital Eye Centre, 2008–2020

YearAll cataract surgeriesSame-day surgeryOne eye at a time cataract surgeries20082826230 (8%)2596 (92%)20092417260 (11%)2157 (89%)20102732594 (22%)2138 (78%)20112829582 (21%)2247 (79%)201236311282 (35%)2349 (65%)201345762502 (55%)2074 (45%)201444832434 (54%)2049 (46%)201553982936 (54%)2462 (46%)201657563252 (56%)2504 (44%)201753242856 (54%)2382 (44%)201853863004 (56%)2382 (44%)201959403536 (60%)2404 (40%)202054023422 (63%)1980 (37%)total56 700 (100%)26 890 (47%)29 810 (53%)	Surgenes fumpere oniversity hospital Lye centre, 2000-2020			
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	2019	5940	3536 (60%)	2404 (40%)
total 56 700 (100%) 26 890 (47%) 29 810 (53%)	2020	5402	3422 (63%)	1980 (37%)
	total	56 700 (100%)	26 890 (47%)	29 810 (53%)

undergoing unilateral and 21 children undergoing bilateral cataract operations of which 8 underwent same-day surgery (38% of bilateral surgeries). The youngest child undergoing same-day bilateral surgery was 6.5 years old. In 54 eyes (64%), posterior capsulotomy and anterior vitrectomy was performed via pars plana during cataract surgery. The youngest patient undergoing cataract surgery where posterior capsule was left intact was 5 years old.

During the 13-year study period, 176 endophthalmitis cases for any aetiology were treated in Tays Eye Centre. The charts of all these cases were reviewed. No cases of postcataract surgery endophthalmitis (n=0; 0%) were found in the 56 700 operations performed in Tays Eye Centre. Nineteen cases with postcataract surgery endophthalmitis were referred from other eye hospitals to Tays Eye Centre. Of these 19 cases, in 13 cases (68%) vitreous samples were culture positive. The causative species were *E. faecalis* (n=5), Coagulase negative Staphylococcus (n=4), Streptococcus viridans (n=3) and Moraxella (n=1). In all these cases, intracameral cefuroxime was used for endophthalmitis prophylaxis except for one patient in whom Moraxella was the causative organism and no information was available on usage of intracameral antibiotic. No cases of haemorrhagic occlusive retinal vasculitis (HORV) were found.

The population of Pirkanmaa Hospital District increased 9% between 2008 (482 000) and 2020 (523 000), while the number of ≥ 65 -year-old inhabitants increased from 81200 (17%) to 115480 (22%). In 2008, the number of cataract surgeries performed in Tays Eye Centre was 2826 and another 900 cataract operations were outsourced to private practice. The latter were omitted after Eye Centre moved into new tailormade facilities in 2012. The number of cataract surgeries organised by Eye Centre was 7.7 per 1000 inhabitants and 46 per $1000 \ge 65$ -year-old inhabitants in 2008. During the study period, the number of cataract surgeries increased gradually between 2008 and 2019. In 2019, there were 5940 cataract surgeries performed in Eye Centre. The number of cataract surgeries were 11 per 1000 inhabitants and 51 per 1000≥65-year-old inhabitants in 2019 (30% and 11% increases from 2008, respectively). In 2020, there was a decrease in number of operation due to closure of cataract clinic at the beginning of COVID-19 epidemic (table 3).

DISCUSSION

To improve access to cataract surgery, there has been a shift towards performing ISBCS.⁷ A series of 141 patients in Finland in 2004, reported safety of ISBCS in experienced hands and substantial savings in healthcare and non-health-care-related costs.^{3 8} These findings are confirmed in our report including 56700 consecutive operations over 13-year period. The annual percentage of ISBCS patients increased from 4% to 46% during the study period with streamlined usage of operating room resources and increase of yearly number of operations.

Within a capitated healthcare system of Kaiser Permanente Northern California in 2016, 92 (86%) of 107 active cataract surgeons reported practising ISBCS with patient convenience and request as the top reasons.⁷ Their most common concerns were missing the postoperative refractive outcome from the first eve to guide IOL selection in the second eve, and the risk of bilateral vision loss. For comparison, a year earlier, the ASCRS Survey reported that nearly 80% of the US cataract surgeons and 2000 global ASCRS members never practice ISBCS.⁹ It has also been suggested that the reimbursement rules may have a role in slowing down the shift to the ISBCS.¹⁰ It may be difficult to persuade physicians to adopt cost-effective practices if the incentive structures oppose such behaviour.¹¹ Tays Eye Centre as a Finnish tax-funded university hospital has a fixed yearly budget and all ophthalmologists have fixed salary. The National Health Service in the UK is also tax-funded and fixedsalaried system. However, although the UK report of December 2019 emphasises the need for developing higher-volume cataract surgical lists, ISBCS is not even mentioned as a tool to increase the throughput.¹²

It is widely acknowledged how different conclusions continue to be drawn from the same and expanding evidence, depending on different cultures and decision-making policies.¹³ This applies not only to ISBCS but also to the selection of antibiotics for prophylaxis of endophthalmitis. The 2017 Cochrane review found five studies meeting the inclusion criteria for reviewing perioperative antibiotics for prevention of acute endophthalmitis after cataract surgery.⁶ These five studies used different antibiotic prophylaxis and included a total of 101005 adults with 132 endophthalmitis cases (0.13%). The review showed high-certainty evidence that injection with cefuroxime with or without topical levofloxacin reduces the incidence of endophthalmitis.⁶ Despite this evidence, the ASCRS 2021 survey reported that only 66% of respondents used intracameral antibiotic prophylaxis.¹⁴

Although the sample size in the Cochrane review was very large, the heterogeneity of the study designs and modes of antibiotic delivery made it impossible to conduct a formal meta-analysis.⁶ In spite of that, in 2018, meta-analysis of 17 observational studies with over 900 000 eyes was performed to compare the efficacy of intracameral cefuroxime, moxifloxacin and vancomycin.⁵ The analysis favoured antibiotics at the end of cataract surgery with no difference between antibiotics in secondary analysis, although the incidence of postoperative endophthalmitis was the lowest with vancomycin.⁵ In the meta-analysis, there was no difference in efficacy between intracameral plus topical antibiotics versus intracameral alone.⁵ In contrast to that, according to the Cochrane review, there was moderate-certainty evidence to suggest that using topical antibiotic eye drops in addition to antibiotic injection probably lowers the incidence of endophthalmitis compared with using injections or topical eye drops alone.⁶ We found no cases of endophthalmitis when using intraocular vancomycin in 56700 consecutive, unselected

cataract surgeries of which over 40 000 were performed without preoperative topical antibiotics, which suggests that they are not needed for effective prophylaxis.

Although there were no endophthalmitis after operations performed in Tays Eye Centre, 19 cases of endophthalmitis were treated in patients who had cataract surgery performed in other public and private eye clinics, which had used intracameral cefuroxime as antibiotic prophylaxis in most cases. The most common pathogen isolated in these cases was *E. faecalis*, which is known to be resistant to cefuroxime and highly virulent resulting in poor visual outcomes.¹⁵ This finding is in accordance with data from a Swedish national cataract registry, which showed that cefuroxime lowered incidence of endophthalmitis from 0.18% to 0.044%, but at the same time there was a shift of causative pathogens away from coagulase negative staphylococcus towards to more virulent species such as *E. faecalis*.¹⁶

Intraocularly administered vancomycin has been associated with a rare but devastating retinal condition, HORV.¹⁷⁻¹⁹ In a report of 23 patients (36 eyes) with HORV, three patients had known prior exposure to vancomycin.¹⁹ The latter and the fact that HORV seems to be worse in the second eye undergoing cataract surgery with vancomycin led to suggesting immunemediated type III hypersensitivity reaction. However, more recent histopathological evidence from an enucleated eye with HORV showed absence of immune complexes in retinal vessels and histopathological findings more consistent with type IV hypersensitivity reaction similar to Stevens-Johnson syndrome.²⁰ If HORV is immune complex-mediated disorder, prior exposure to vancomycin could be a risk factor. On the other hand, if HORV were type IV hypersensitivity mediated, genetic factors are likely to play a bigger role when assessing the risk of HORV. Since HORV is a remarkably rare event, no epidemiological data are available regarding the difference of incidence rates.

We could see neither endophthalmitis nor HORV in 56700 cataract operations performed with vancomycin prophylaxis during 13 years. These long-term favourable results obviously make the decision to change prophylactic measures extremely challenging—simultaneously being more than aware of the increasing probability of any severe postoperative complication. Although the risk of HORV is lower compared with that of endophthalmitis, it is likely that if the risk will realise in ISBCS, HORV will more likely be bilateral compared with endophthalmitis. Due to this potential risk of bilateral blindness associated with use of vancomycin, in 2021, Tays Eye Centre adopted a policy of different intracameral antibiotics to be used per eye in ISBCS and cataract surgeries performed in separate sessions within 1 month.

As a result of the COVID-19 pandemic, ISBCS gained new and increasing interest to reduce potential infection exposure risk by decreasing number of visits for surgery and follow-up by half. This study is one of the largest to report experiences on ISBCS in real-life clinical practice. The frequency of ISBCS increased gradually over 13-year period reflecting surgeons' accumulating experience of performing ISBCS and evidence on safety profile of ISBCS as well as patient satisfaction and awareness on ISBCS. Limitations of the current study include absence of information on visual outcomes and postoperative complications other than endophthalmitis. This information is not available since postoperative visits are not arranged after uneventful cataract surgery by Tays Eye Centre. Furthermore, it is of note that this study does not address the question, what is the optimal antibiotic to prevent postoperative endophthalmitis.

In spite of cataract surgery being the most common surgical procedure, there are very few high-quality RCTs of infection

control interventions because of the rarity of this complication and the large sample size therefore needed. We will therefore need to try to draw conclusions derived from observational studies of real-life practices such as this study. Although this may explain the variability of interpretations of the published evidence, the clinical policies are still amazingly different. As current information technologies allow automated recording of the important parameters and clinical measures, all real-world data need to become available for national and international benchmarking purposes in search for optimal level of care within an affordable healthcare system.¹³

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Contributors AV, AT and HU-J designed the research. PH, TF, EL, US, HH, MH and HS analysed the data. AT, HU-J and PH wrote the manuscript. PH made the tables. All the authors reviewed the paper. HUJ is responsible for the overall content of the study.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants but as the patient identifiers were removed after the data collection, the ethics committee of Pirkanmaa Hospital District determined that formal ethics approval was not required. This is a retrospective study.

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ORCID iDs

Pekko Hujanen http://orcid.org/0000-0002-5932-1568 Heini Huhtala http://orcid.org/0000-0003-1372-430X Hannele Uusitalo-Järvinen http://orcid.org/0000-0002-2030-295X

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