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Simultaneous Bilateral Phacoemulsification and Cataract Extraction – A New Operation Method

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Abstract

Purpose: To investigate the safety of a new simultaneous bilateral phacoemulsification and cataract extraction method.

Setting: Two public hospitals and two private hospitals, Finland.

Design: Four center retrospective cohort study.

Methods: The study group consisted of all simultaneous bilateral phacoemulsification and cataract extraction operations conducted between 2009-2019 by one senior surgeon at one public hospital (2648 eyes) and at two private hospitals (1152 and 932 eyes). The control group was immediately sequential bilateral cataract surgeries (ISBCS) performed at one public hospital by several senior surgeons between 2017-2018 (4854 eyes). The primary outcome was the difference in incidences of early postoperative complications in individuals. Secondary outcomes included intraoperative complications and re-operations due to complications.

Results: The study group was non-inferior in all the controlled postoperative complications compared to ISBCS ($p < 0.05$) at both the 0-3 months and 0-12 months follow-up, except for cystic macular edema (CME) ($p = 0.08$) that tended to be more common in the study group at 0-12 months. There were no differences in intraoperative complications between the study group and the control group ($p = 0.68$).

Conclusion: The studied simultaneous bilateral phacoemulsification and cataract extraction method is non-inferior to the prevailing standard technique of ISBCS.

Introduction

The demand for cataract surgeries is high and rising in the future [1]. Therefore, every way that can make cataract operation process lighter and faster in a safe manner is a keen interest among ophthalmologists to replace the delayed sequential bilateral cataract operation (DSBCS) with the immediate bilateral cataract surgery (ISBCS). In DSBCS the two surgeries are performed at two separate time points and in ISBCS the cataract surgery is performed on both eyes during the same session but as two totally separate procedures. Ophthalmologists and patients' attitude towards ISBCS have slowly become more positive as there is a growing number of reports of the safety of ISBCS compared to DSBCS [1-13].

In this study we analyse a new method to perform bilateral cataract surgery. In this new method the operation is done on both eyes in one session using a separate set of sterile instruments for each individual eye without re-draping the patient and without re-gowning and re-gloving the operator and the assistant and without changing the batches of consumables between the eyes. This new method could produce savings in the limited healthcare resources by needing less materials and being less time consuming. To date there are no publications on this method.

The aim of this retrospective real-life study is to investigate the safety of this new surgical method in western Finland. This is done by comparing the safety of the bilateral cataract operations performed with this new method by one

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experienced surge onto ISBCS´s conducted at one public hospital by several experienced surgeons.

Materials and Methods

Surgical method

In the new simultaneous bilateral phacoemulsification and cataract extraction method the operation is conducted on both eyes in one session using a separate set of sterile instruments in each individual eye without re-draping the patient and without re-gowning or re-gloving the operator or the assistant nurse and without changing the batches of the consumables between the eyes.

Instruments for both eyes are prepared at the same table but are completely separated from each other. All the instruments, including phaco-handpieces and irrigation-aspiration handpieces are prepared to be ready for use. Instruments for the second eye are then covered with a sterile cover. The phacoemulsificator is prepared for the first eye.

The patient is draped with a surgical drape planned for a cataract operation. The drape has two bags, one on each side of the surgical opening, which is manually enlarged so that both eyes are visible through the opening. Eyelids and lashes are draped with a transparent film, separately for upper and lower lids on both sides. Before starting the surgery for the first eye, the second eye is covered with a lidocaine hydrochloride 2% gel to keep it moist during the operation on the first eye.

During the operation on the first eye one end of the phacoemulsificator preparation table is used for keeping the connected handpieces in a sterile place and available for the surgeon. The first eye is then operated with a standard technique and finally an intracameral antibiotic is injected. Cefuroxime was the most usual antibiotic used.

After the operation the first eye it is covered with a lidocaine hydrochloride 2% gel to keep it moist during the operation of the second eye. Handpieces are either removed from the phacoemulsificators preparation table and placed together with the first eyes instruments on the instrument table, or they are kept in place during the operation of the other eye. Drapes for the phacoemulsificator monitor and preparation table are not changed. The phacoemulsificator cassette is not changed and the new phaco-handpiece for the second eye is connected to the same cassette system. The new phaco-handpiece is then tuned for surgery. During the operation of the second eye the handpieces are held at the opposite end of the preparation table compared with the hand pieces for the first eye.

Neither the nurse nor the surgeon is re-gowned and same surgical gloves are used during the whole procedure for both eyes. Patient´s drape is not changed. The drape that covered the instruments for the second eye´s operation is now moved to cover the instruments for the first eye.

The operation on the second eye is started by flushing the lidocaine hydrochloride gel away with a balanced salt solution. Then the rest of the operation is conducted using the standard technique. During the operation on the second eye the surgeon and assistant nurse consciously avoid touching the tips of the instruments that are being put inside the eye during the operation.

During the study, individuals in the study group used preoperatively topical dexamethasone 1 mg/ml + chloramphenicol 2 mg/ml combination preparation six times daily for one day before the operation on both eyes. In the control group the preoperative treatment consisted of levofloxacin 5 mg/ml six times daily for one day before the operation on both eyes. The postoperative routine topical medication used in the study group was a combination preparation dexamethasone 1 mg/ml + chloramphenicol 2 mg/ml applied 3-4 times daily for one month. In the control group the postoperative treatment consisted of levofloxacin 5 mg/ml four times daily for one week and dexamethasone 1 mg/ml four times daily for one month.

The periocular area was perioperatively disinfected either with denatured ethanol w-10%/12 vol-% or with denatured ethanol 80%. The disinfection method in the control group was conjunctival povidone-iodine (5%) with denatured ethanol w-10%/12 vol-% to disinfect the periocular skin.

Patient selection and collected data

Ethical approval was not required for this study in accordance with the ethical review that was performed by the Ethics Committee for Human Sciences at the University of Turku. This study followed the tenets of the Declaration of Helsinki. As the study was retrospective observational register study patient consent were not required in accordance with local guidelines. Study permission was granted by the chief officers of all the organizations responsible for registries from which the data was collected.

The study group consisted of all simultaneous bilateral phacoemulsification and cataract extraction operations carried out between 25.8.2009-11.12.2019 by one senior surgeon. Operations were done at one public hospital (1324 individuals, 2648 eyes) and at two private hospitals (576 and 466 individuals, 1152 and 932 eyes respectively). In 38 of the operations performed in public hospital the senior surgeon was the principal operator and was teaching new trainees. All the operations in private hospitals were done by the senior surgeon. The control group was ISBCSs operated at a university hospital by several senior surgeons between 1.1.2017 and 31.12.2018 consisting of 2427 individuals (4854 eyes).

Data was retrieved retrospectively from the electronic or physical records of each hospital. The data collected comprised: Date of the operation, age at the time of the operation, gender, type of intraocular lens inserted, the diagnoses of preoperative risk factors (International Classification of Diseases 10, ICD-10) or operation codes (NOMESCO Classification of Surgical Procedures, NCSP) or mentions in referrals, the operational timestamps available, intraoperative complications (NCSP) codes, biometrical values in both eyes (keratometry min, keratometry max, axial length), preoperative refraction, postoperative refraction

when available, the date and postoperative nature of the diagnosis in postoperative visits (ICD-10) both at 0-3 months and 3-12 months postoperatively, the date of additive operations during a 0-12 months postoperative period, extra operation codes (NCSP) and possible death dates.

To determine reliable incidences of possible severe postoperative complications, any possible postoperative visits and re-operations were monitored not only from the hospitals where the operations were done, but also by the individuals' regional public central hospitals.

No separate preoperative visit due to the planned cataract operation was scheduled in the study group operated at a public hospital. The preoperative evaluation was done based on the referrals sent by private ophthalmologists. If there was a suspicion according to the referral that the patient would be unsuitable for a cataract operation under topical anaesthesia (e.g. severe memory disorder, severe Parkinson´s disease or mental retardation) the patient was called for a preoperative evaluation. At private hospitals the surgeon examined the patients planned for simultaneous bilateral phacoemulsification and cataract extraction operation before surgery and in the control group all the patients were evaluated preoperatively at university hospital by young training ophthalmologists.

The main outcome measures were cumulative incidences of postoperative complications at 3 months and at 12 months. A search for the number of postoperative visits and the most severe postoperative complications was carried out using diagnoses (ICD-10). The complications included in the analysis were endophthalmitis, postoperative cystic macular edema (CME), retinal detachment, corneal decompensation, persistent postoperative anterior uveitis, malignant glaucoma and the change of dry macular degeneration into exudative macular degeneration. In both groups, individuals alive at the end of the observation period were included in the analyses. Secondary outcomes included intraoperative complications and re-operations due to complications. Searches were made for intraoperative complications using extra operation codes (NCSP), and the possible re-operations were searched for by using operation codes (NCSP) combined with the search for postoperative complication diagnoses (ICD-10). Vitrectomies due to retinal detachment or cystic macular edema, intravitreal injections due to cystic macular edema and anterior chamber lavation were noted.

Statistical analysis

Differences in continuous variables were assessed with two-sided unpaired t-tests and differences in categorical variables with Fisher's exact test. The non-inferiority analysis for the risk difference in post-operational complications of the study group compared to the control group was based on the two-sided 90% confidence limits obtained by the Farrington-Manning method, this is equivalent to upper one-sided 95% confidence limits and a significance level of 0.05. In determining the margins for those non-inferiority tests, we did not allow for any excess complications in the study population as compared to the control population but protected us from random sampling variation in post-operational complications as follows. Reference values were obtained for the relative incidences *p* for the considered post-operational complications within the considered timeframes from the literature. If both the study group and the control group share that common incidence, then the number of complications in both samples are binomially distributed with parameters $n_{S/C}$ and p, where n_S and n_C denote the sample size of the study and control group, respectively. As a result, the difference in observed relative incidences between the samples is asymptotically normally distributed with zero mean and standard deviation $\sqrt{p(1-p)\left(1/n_S + 1/n_C\right)}$. A positive margin of 1.645 times that standard deviation was allowed consistent with the construction of a two-sided 90% (respective one-sided 95%) confidence interval for the difference of incidences out of sample when the observed incidences in both the study and the control groups are *p*. The analyses were performed using the SAS System, version 9.4 for Windows (SAS Institute Inc., Cary, NC, USA). A p-value of 0.05 or less was considered significant.

Results

Preoperative analysis

The study group consisted of 2366 individuals (4732 eyes), the control group of 2427 individuals (4854 eyes). The baseline characteristics of the individuals (Table 1) and preoperative risk factors (Table 2) were comprehensively evaluated. Although there were statistically significant differences in many of the baseline variables due to the large amount of data, no clinically meaningful differences were observed. There was less missing baseline data in the control group. The proportion of missing data is greater in the study group partly due to the fact that the biometrical values were not integrated into electronic records and were saved in physical archives. The amount of missing data was considered small and randomly distributed.

Preoperative risk factors were evaluated by diagnose codes (ICD-10) and by preoperative refractive surgery operation codes (NCSP) or mentions of refractive operations in referrals. When the study group was compared to the control group, there were statistically significantly more individuals with uveitis, glaucoma suspicion, glaucoma, mature cataracts, diabetic eye disease and prior refractive surgeries in the study group. In the control group there were statistically significantly more individuals with dry macular age-related degenerations and memory disorders than in the study group.

Intraoperative analysis

Anterior vitrectomies were performed on 3 eyes of 3 (0.06%) individuals in the study group. In the control group, 2 eyes of 2 individuals (0.04%) anterior vitrectomies were performed. The difference was not statistically significant (p = 0.68, Fisher´s Exact test).

No choroidal effusions were diagnosed in the study group nor the control group.

Table 1: Baseline characteristics of the groups.

Characteristics	Study group	Bilateral control group	P-value[c)]
Total number of patients, n	2366	2427	
Age at surgery (y), mean ± SD	76.0 ± 9.6	75.6 ± 8.2	0.07[a)]
min (y)	33.0	34.0	
max (y)	102.0	97.0	
Female sex (%)	1474 (62.3)	1475 (60.8)	0.29[b)]
AL. mean ± SD			
right eye	23.57 ± 1.38	23.61 ± 1.15	0.33 [a)]
data missing, n (%)	51 (2.16)	7 (0.29)	
left eye	23.52 ± 1.34	23.58 ± 1.15	0.08 [a)]
data missing, n (%)	55 (2.32)	7 (0.29)	
Keratometry (D), mean ± SD			
Right eye	43.84 ± 1.61	43.73 ± 1.49	0.01[a)*]
min (D)	34.00	36.75	
max (D)	54.97	53.74	
data missing, n (%)	48 (2.03)	6 (0.25)	
Left eye	43.93 ± 1.62	43.79 ± 1.48	0.001 [a)*]
min (D)	36.25	36.64	
max (D)	55.51	50.45	
data missing, n (%)	51 (2.16)	7 (0.29)	
Preoperative refraction SE (D). mean ± SD. (min, max)			
right eye	0.1 ± 3.39 (-19.13, +9.50)	-0.21 ± 2.90 (-16.50, +8.13)	< 0.001[a)*]
data missing, n (%)	51 (2.16)	28 (1.15)	
left eye	0.17 ± 3.29 (-20.38, +9.5)	-0.14 ± 2.88 (-16.38, +10.75)	< 0.001[a)*]
data missing, n (%)	44 (1.86)	40 (1.65)	

a) t-Test.AL=axial length, b) Fisher´s exact test, D = diopter, n = number of patients, SD: Standard Deviation; SE: Spherical Equivalent; y = years, *= statistically significant

Table 2: Preoperative risk factors in the groups.

Complicating factor. n (%)	Study group	Control group	p-value
Corneal scar, n (%)	18 (0.75)	12 (0.49)	0.27[a)]
Corneal dystrophy, n (%)	50 (2.11)	36 (1.48)	0.10[a)]
Uveitis, n (%)	6 (0.25)	0 (0.00)	0.01[a)*]
Pseudoexfoliation syndrome, n (%)	144 (6.09)	180 (7.42)	0.07[a)]
Glaucoma suspicion, n (%)	94 (3.97)	37 (1.52)	< 0.001[a)*]
Glaucoma, n (%)	171 (7.23)	71 (2.93)	< 0.001[a)*]
Facodonesis, n (%)	2 (0.08)	1 (0.04)	0.62[a)]
Mature cataract, n (%)	53 (2.24)	16 (0.66)	<0.001[a)*]
Dry AMD, n (%)	365 (15.43)	429 (17.68)	0.04[a)*]
Exudative AMD, n (%)	32 (1.35)	22 (0.91)	0.17[a)]
Diabetic eye disease, n (%)	43 (1.82)	5 (0.21)	< 0.001[a)*]

Retinal degenerations, treated tears, n (%)	23 (0.97)	31 (1.28)	0.34[a)]
Vitrectomized eye, n (%)	10 (0.42)	3 (0.12)	0.05[a)*]
Prior refractive surgery, n (%)	15 (0.63)	4 (0.16)	0.01[a)*]
Prior ocular contusion, n (%)	2 (0.08)	4 (0.16)	0.69[a)]
Morbus Parkinson, n (%)	15 (0.63)	24 (0.99)	0.20[a)]
Memory disorders, n (%)	42 (1.78)	82 (3.38)	< 0.001[a)*]
Total number of complicating factors per patient, n (%)			
Mean ± SD	0.49 ± 0.61	0.39 ± 0.61	< 0.001[b)*]
0	1423 (60.14)	1616 (66.58)	
1	811 (34.28)	679 (27.98)	
2	123 (5.20)	119 (4.90)	
3	8 (0.34)	12 (0.49)	
4	1 (0.04)	1 (0.04)	

a) Fisher´s exact test, AMD: Age Related Macular Degeneration, b) t-Test, n = number of patients, *= statistically significant

Table 3: Postoperative complications 0-3 months postoperatively, in individuals alive at 3 months.

Postoperative complication, n (%), [95% C.I.]	Study group	Control group	p-value[a)]
Endophthalmitis	0 (0.00) [0.00, 0.08]	0 (0.00)	> 0.99
Postoperative CME	17 (0.36) [0.23, 0.58]	11 (0.23)	0.26
- bilateral	4 (0.08)	4 (0.08)	> 0.99
Persistent anterior uveitis	12 (0.25) [0.15, 0.45]	14 (0.29)	0.85
- bilateral	3 (0.06)	2 (0.04)	0.68
Retinal detachment	2 (0.04) [0.01, 0.15]	2 (0.04)	> 0.99
- bilateral	0 (0.00)	1 (0.02)	> 0.99
Corneal decompensation	0 (0.00) [0.00, 0.08]	5 (0.10)	0.06
- bilateral	0 (0.00)	4 (0.08)	0.13
Dry AMD progression to exudative AMD	15 (0.32) [0.19, 0.53]	21 (0.43)	0.41
Malignant glaucoma	0 (0.00) [0.00, 0.08]	0 (0.00)	> 0.99
Totally postoperative all complications, n (%)	46 (0.98)	53 (1.10)	0.61
Without postoperative complications, n (%)	4662 (99.02)	4779 (98.90)	0.61
Totally postoperative complications, AMD Excluded n (%)	31 (0.66)	32 (0.66)	> 0.99
Without postoperative complications, AMD Excluded n (%)	4677 (99.34)	4800 (99.34)	> 0.99
Patients died before the end of the follow up time, n (%)	12 (0.51)	11 (0.45)	0.84
Operated eyes	4708	4832	

a) Fisher´s exact test, AMD: Age Related Macular Degeneration; CME: Cystic Macular Edema; n = number of patients, 95% C.I.= 95% confidence interval,*= statistically significant

Postoperative analysis

The incidence of postoperative complications in the study group and in the control group at a 3 or 12-month follow-up are shown in Table 3 and Table 4. There were no statistically significant differences in survival rates between the groups. The total number of postoperative complications did not differ between the study group and the control group in either of the follow-up periods; 0-3 and 0-12 months ($p > 0.99$ and $p = 0.62$ respectively).

At 3 months postoperatively, there were no statistically significant differences in the incidences of postoperative complications between the study group and the control group. Non-inferiority testing showed that the study group was non-inferior in all the postoperative complications controlled for when compared to control group as shown in Table 5.

At 12 months postoperatively there were no statistically significant differences in the incidences of postoperative complications between the study group and the control group. Non-inferiority testing indicated that the study group was non-inferior in all the controlled postoperative complications except for CME when compared to the control

Table 4: Cumulative postoperative complications 0-12 months postoperatively, among individuals alive at 12 months.

Postoperative complication, n (%), [95% C.I.]	Study group	Control group	p-value[a)]
Endophthalmitis	0 (0.00) [0.00, 0.08]	0 (0.00)	> 0.99
Postoperative CME	25 (0.54) [0.37, 0.80]	18 (0.38)	0.29
- bilateral	5 (0.11)	6 (0.13)	> 0.99
Persistent anterior uveitis	20 (0.44) [0.28, 0.67]	18 (0.38)	0.75
- bilateral	7 (0.15)	6 (0.13)	0.79
Retinal detachment	6 (0.13) [0.06, 0.28]	5 (0.11)	0.77
- bilateral	0 (0.00)	1 (0.02)	> 0.99
Corneal decompensation	1 (0.02) [0.004, 0.12]	7 (0.15)	0.07
- bilateral	0 (0.00)	4 (0.08)	0.13
Dry AMD progression to exudative AMD	36 (0.78) [0.57, 1.08]	28 (0.59)	0.32
Malignant glaucoma	0 (0.00) [0.00, 0.08]	0 (0.00)	> 0.99
Totally postoperative all complications, n (%)	88 (1.92)	76 (1.61)	0.27
Without postoperative complications, n (%)	4504 (98.08)	4642 (98.39)	0.27
Totally postoperative complications, AMD Excluded, n (%)	52 (1.13)	48 (1.02)	0.62
Without postoperative complications, AMD Excluded, n (%)	4540 (98.87)	4670 (98.98)	0.62
Patients died before the end of the follow up time, n (%)	70 (2.96)	68 (2.88)	0.80
Operated eyes	4592	4718	

a) Fisher´s exact test, AMD: Age Related Macular Degeneration; CME: Cystic Macular Edema; n = number of patients, 95% C.I.= 95% confidence interval, *= statistically significant

Table 5: Non-inferiority testing of postoperative complications without clinical marginals but including statistical marginals to allow for sampling variation. The upper limits of the two-sided 90% confidence intervals coincide with the upper limits of one-sided 95% confidence intervals for the risk difference study group vs. control. P-values below 0.05 establish non-inferiority of the study group.

Postoperative complication	Reference incidence (%)	Reference implied marginal (%)	Upper 90% (%)	p-value[a)]
0-3 months postoperatively				
Postoperative CME	1.17	0.36	0.33	0.03*
Persistent anterior uveitis	1.75	0.44	0.18	0.01*
Retinal Detachment	0.25	0.17	0.11	0.01*
Corneal decompensation	1.00	0.33	0.05	< 0.001*
Dry AMD progression to exudative AMD	0.60	0.26	0.11	0.002*
Malignant glaucoma	0.60			
0-12 months postoperatively				
Postoperative CME	1.17	0.37	0.40	0.08
Persistent anterior uveitis	1.75	0.45	0.24	0.001*
Retinal Detachment	0.43	0.22	0.17	0.01*
Corneal decompensation	1.00	0.34	0.04	< 0.001*
Dry AMD progression to exudative AMD	2.40	0.52	0.48	0.03*
Malignant glaucoma	0.06			

a) Farrington-Manning method, AMD: Age Related Macular Degeneration; CME: Cystic Macular Edema, *= statistically significant

group as shown in Table 5.

Individuals with bilateral complications are listed in Table 3 and Table 4. In the study group, all the individuals with persistent bilateral uveitis but one with other macular pathologies gained normal visual acuity after treatment. In the study group all individuals with bilateral persistent uveitis gained normal visual acuity after treatment. One individual with bilateral retinal detachment was observed in the control group one month postoperatively. After retinal surgery the visual acuity of this individual remained normal in both eyes.

Table 6: Re-operations during the 0-12 months postoperative follow-up.

Operation, n (%)	Study group	Control group	p-value[a)]
Vitrectomies			
Totally	1 (0.02)	5 (0.11)	0.22
RD	1 (0.02)	3 (0.06)	0.63
CME	0 (0.00)	2 (0.04)	0.50
Intravitreal injections			
CME	3 (0.07)	1 (0.02)	0.37
Anterior chamber cleaning due to lens remnants	1 (0.02)	2 (0.04)	> 0.99
1 re-operation	2 (0.04)	7 (0.15)	0.18
2 re-operations	0 (0.00)	2 (0.04)	0.50
Operated eyes	4592	4718	

a) Fisher´s exact test, CME: Cystic Macular Edema, n = number of patients, RD: Retinal Detachment

In the control group four individuals with bilateral corneal oedema were observed, one with a predisposing bilateral cornea guttata. All the other eyes gained normal visual acuity after treatments, but one cornea remained oedematous, and required partial thickness corneal transplant surgery.

The number of re-operations done during the first 12-month postoperative period is shown in Table 6. There were no statistically significant differences between the groups. The time (mean ± SD) of the re-operation was 65.50 ± 65.76 days (min 19, max 112 days) in the case of the study group and 284.40 ± 51.59 days (min 223, max 342 days) in the control control group.

Discussion

The main reasons why ophthalmologist do not perform ISBCS routinely in Europe are the risk of bilateral endophthalmitis and medicolegal issues should the ISBCS not succeed [1]. Anyhow the popularity of the ISBCS has been slowly rising. This is due to the growing amount of evidence on the safety of ISBCS as it has been considered as safe a procedure as the DSBCS. Current opinion on safety and effectiveness of ISBCS originate from careful patient selection, strict aseptics, independent surgery of both eyes and high surgical expertise [5,7-11].

This study investigated if simultaneous bilateral phacoemulsification and cataract extraction protocol could be developed so that the operation is done on both eyes in one session using a separate set of sterile instruments for each individual eye without re-draping the patient and without re-gowning and re-gloving the operator and the assistant and without changing the batches of consumables between the eyes is. In this way the operation process could be less time and material consuming without increasing the risks of the possible complication. To compare the new method with the standard method of ISBCS a non-inferiority testing was chosen, and it showed the new method is at least equally safe when compared with the prevailing standard technique of ISBCS concerning the most difficult and frightened postoperative complications. From an ethical point of view, when there is a possibility of severe bilateral complications, each individual case needs to be assessed separately. The autonomy of an individual is the key factor in decision making on a possible ISBCS [14]. Ethical considerations concerning ISBCS have stated that the primary benefits are centred on patient convenience factors and the cost savings to healthcare services are considered as a secondary benefit [7,14]. It is considered that the possible sight-threatening complications outweigh the possible benefits of the ISBCS [15,16]. Such complications are usually mentioned as bilateral endophthalmitis, bilateral corneal oedema, bilateral macular cystoid edema and refractive surprises [15,16]. In more complicated cases when general anaesthesia (especially high-risk general anaesthesia) is needed the attitude towards ISBCS is more acceptable [1,3,13].

Endophthalmitis is a rare, but a potentially blindness causing, complication. Preoperative antiseptic preparation of the periocular skin, most commonly done with povidone-iodine, has been shown to reduce the risk of endophthalmitis [17]. One of the most important factors reducing the incidence of postoperative endophthalmitis is the use of intracameral antibiotics at the end of the surgery [18-20]. With strict asepsis and the use of intracameral antibiotics the incidence of postoperative acute endophthalmitis has reduced to as low as 0.0152 (95% CI 0.0072-0.0231) to 0.12 (CI 95% 0.08%-0.181%) [17,20-23]. Some cases of bilateral endophthalmitis after ISBCS have been published [24,25]. However, the risk of postoperative endophthalmitis in ISBCS has been reported to be at least as low as for unilateral cataract surgery [23,26-28]. In this study no postoperative endophthalmitis was diagnosed in the study group or the control groups. With this sample size it can be concluded that the studied method seems to be non-inferior compared to control group.

Postoperative macular edema (CME) has been shown to be a common etiology in suboptimal visual outcome, an overall incidence of clinically significant CME being 1% to 2% in eyes with uneventful cataract operations [29]. It is known that for example diabetes, retinal vein occlusion, epiretinal membrane, intraoperative complications and the use of pupil expansion device increase the risk of postoperative CME [29-32]. The role of preoperative prostaglandin analogue use

and the pseudoexfoliation syndrome remain controversial as independent risk factors for postoperative CME [33,34]. The peak incidence of postoperative CME due to cataract surgery is during the 0-3 months postoperative period [29,32]. This study demonstrated that the study group was non-inferior to the control group in the 0-3 months postoperative period. This remained the case despite the higher proportion of individuals with uveitis, diabetic eye disease, preoperatively vitrectomized eyes, mature cataract and glaucoma in the study group. The non-inferiority to ISBCS could not be demonstrated in the 0-12 months follow-up (p = 0.08). As the search for complications was conducted by diagnoses there is a possibility that there could have been other causes of CME during the 3-12 months period than the cataract operation. This could also partly be due to the differences in predisposing factors (e.g. preoperative uveitis) and due to the strict attitude to any - clinically probably justified - excess complications. In this study individuals with bilateral CME are listed in Table 3 and Table 4. In the study group, all individuals gained normal visual acuity after treatment. In the control group all gained the anticipated visual acuity after treatment. Three individuals were left with subnormal visual acuity which was caused by ocular co-morbidities; diabetic eye disease, preretinal membrane or dry macular degeneration.

This study demonstrated that the new method was non-inferior when compared to the ISBCS regarding all the other postoperative complications controlled for. This research was a retrospective study and gathered information from locations where electronic patient records were not used to save all the data. This meant that certain information was missing for some of the individuals, for example, due to lost papers in the manual archiving processes. Individuals were preoperatively evaluated in the control group by training ophthalmologist and more attention was paid to many kinds of preoperative factors compared to the study group in a public hospital where individuals were usually not preoperatively evaluated; this group relied on private practitioner observations. This can have influenced the prevalence of reported not so crucial risk factors, such as AMD or memory disorders, which were more often found in the control group than in the study group. Searches for the preoperative complicating factors and postoperative complications were conducted electronically. No statistically significant differences were found between the study group and the control group.

Although the data is quite large, to detect rare complications - for example endophthalmitis, the volume would need to be even greater as to make it possible to observe differences between the groups. As a result of this study, the new method is at least as safe as the standard method of ISBCS when performing bilateral cataract operation at one session. In the future, prospective research is recommended to strengthen this conclusion still further.

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Value Statement

What was known: Immediately sequential bilateral cataract operation (ISBCS) is as safe method as delayed sequential bilateral cataract operation (DSBCS).

Careful patient selection, strict aseptic, independent surgery of both eyes and high surgical expertise are the warranted to perform ISBCS.

What this paper adds: Simultaneous bilateral phacoemulsification and cataract extraction with the new studied method is non-inferior technique to ISBCS and DSBCS and solely a safe method to operate both eyes simultaneously.

Conclusion

The studied simultaneous bilateral phacoemulsification and cataract extraction method is non-inferior to the prevailing standard technique of ISBCS.

Conflict of Interest

None.

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