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A COHORT STUDY OF 27 CASES OF ENDOPHTHALMITIS AT A SINGLE INSTITUTION

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ABSTRACT

Purpose:

To identify potential risk factors associated with post-cataract surgery bacterial endophthalmitis.

Setting:

The John A. Moran Eye Center.

Design:

Retrospective cohort study.

Methods:

Patient or Study Population: Patients operated on for cataract(s) at this eye hospital.

Intervention or Observation Procedure(s): 10% sampling of all patients operated on for cataract surgery from 1-1-96 to 12-31-02 were compared with all cases of post-cataract surgery bacterial endophthalmitis during this same time period at this institution.

Main Outcome Measure(s): Surgical complication, first postoperative day wound leak, incision placement and location, intraocular lens material, if a suture is placed, antibiotic used, collagen shield use, and whether patched.

Results:

1525 patients were in the control cohort and there were 27 cases of endophthalmitis. In a multivariate regression analysis those factors found to be statistically associated with endophthalmitis were: 1. wound leak on the first postoperative day (O.R. 44 ± 42; C.I 6.85 to 287; P<0.001); 2. capsular or zonular surgical complication (O.R. 17.2 ± 14.2; C.I. 3.44 to 86.4; P=0.001); 3. topical antibiotic started the day after surgery rather than the day of surgery (O.R. 13.7 ± 12.9; C.I. 2.17 to 90.9; P=0.005); 4. use of ciprofloxacin rather than ofloxacin topically after surgery

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(O.R. 5.3 ± 3.6; C.I. 1.41 to 20.0; P=0.014); 5. not patching after surgery (O.R. 7.1 ± 5.6; C.I. 1.47 to 36.4; P=0.015); and 6. not placing a collagen shield soaked in antibiotic (O.R. 2.7 ± 1.3; C.I. 1.06 to 7.14 P=0.037)

Conclusions:

In sutureless cataract surgery, surgical complications and wound leak on the first postoperative day were most strongly associated with endophthalmitis.

Synopsis:

In sutureless clear corneal incisions, complications exposing vitreous or leaky wound was associated with increased endopthalmitis risk. Antibiotics used the day of surgery and a collagen shield soaked in antibiotics were associated with decreased risk.

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INTRODUCTION

Endophthalmitis has historically been about 0.1%[1] and yet sutureless, corneal surgery has been shown in a randomized study to statistically significantly increase this risk[2]. At the same time most institutions have also abandoned subconjunctival antibiotic injections because of the discomfort and have switched to topical fluoroquinolones as the mainstay of antibiotic prophylaxis. All of these changes leave unanswered questions about the best approaches to minimize post-surgical endophthalmitis risk.

In an internal quality control study (Jensen MK, Fiscella RG. Comparison of endophthalmitis rates over four years associated with topical ofloxacin vs. ciprofloxacin. Invest Ophthalmol Vis Sci 2002; 43(12):4429), we found that the choice of antibiotic could be important in the incidence of post-surgical endophthalmitis[3]. This study has now been expanded to a seven-year review representing over 15,000 cataract surgeries at one institution. We have included a control cohort representing 10% of all surgeries and have used original source documents in regard to all information gathered from the cohort control group as well as the endophthalmitis group. We would like to report our results from this retrospective cohort study.

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METHODS

All cataract surgeries (no combined surgeries) between January 1, 1996 and December 31, 2002 at the John A. Moran Eye Center were included in the study. In the same period of time, all cases of bacterial endophthalmitis from our original quality control database were included, as well as a review of all cases with the diagnosis of endophthalmitis, a review of all cases where a culture was taken in the operating room, and all cultures submitted as either aqueous or vitreous culture, to ascertain that we included all cases of bacterial endophthalmitis during the study period.

Every tenth consecutive chart starting from January 1, 1996 of patients operated were reviewed and included in our cohort study. If the clinical chart was not available, then the 9th chart in order was reviewed and if it was not available then the 11th chart was reviewed. Using this system, all charts were available for an exact 10% sampling of all patients.

The information collected on each patient included patient age, gender, date of surgery, surgeon, anesthesia used, preoperative antibiotic used, listing of the surgical complication of capsular rupture or zonular dehiscence, intraocular lens used, whether a suture or collagen shield was used, whether the incision was temporal or superior, whether the incision was scleral or limbal/corneal, whether the eye was patched, postoperative antibiotic used and frequency of use, whether antibiotic was started on the day of surgery, and whether any complication was noted on the first postoperative day (specifically a wound leak). There was no control for surgical technique variations except these that are listed. A collagen shield when used was always soaked in 0.5-ml of cefazolin (100-mg/ml) and 0.5-ml of dexamethasone (4 mg/ml). Antibiotics were not used intraocularly or in the irrigating fluid for any of these cases. Subconjunctival antibiotics were only used in some scleral incision cases. For cases of endophthalmitis, the date that the infection was first noted, the final visual acuity attained, and culture results were also determined.

Because topical Betadine was used prior to surgery in every case, except where the patient was allergic to iodine, this was not a variable that was reviewed. This study had IRB approval and followed all HIPAA regulations.

Data was entered into Microsoft Excel 2000 and imported into STATA version 8 (College Station, TX). Summary statistics were calculated and used to characterize all control and endophthalmitis cases in terms of age, gender, type of anesthesia, type and location of incision, type of IOL, type of pre-operative and post-operative antibiotic, whether a collagen shield was used, suture status of the wound, whether a surgical complication or wound leak was noted, and if antibiotic therapy was started the day of surgery. Incidence of endophthalmitis per surgeon was also determined.

Univariate logistic regression models were used to predict development of endophthalmitis based on each study variable. Multivariate logistic regression was used to examine the development of endophthalmitis among study subjects whereby all factors used in the univariate models were inserted to determine which surgical factors emerge as significantly associated with endophthalmitis development postoperatively.

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RESULTS

1,525 charts were reviewed representing 15,254 cataract surgeries. Incidence of endophthalmitis per surgeon was not statistically different. During this seven-year period of time there were 27 cases of presumed endophthalmitis of which 20 were culture positive. A multi-variant regression analysis was performed but did not include a scleral or superior incision or retrobulbar anesthesia (all three were almost completely concordant) because there were no cases of endophthalmitis for these approaches and, therefore, an odds ratio could not be determined (they predicted success perfectly). Looking, therefore, at all other variables, those that were statistically associated with the diagnosis of endophthalmitis were (Tables 1 & 2):

1. A wound leak noted on the first postoperative day (odds ratio 44.4 ± 42.3; 95% confidence intervals 6.85 to 287.4; P<0.001 for all cases and 21.4 ± 25.7; 95% confidence intervals 2.02 to 226.4; P=0.011 for culture positive cases).
2. Breaking the capsule or zonular dehiscence at the time of surgery (odds ratio 17.2 ± 14.2; 95% confidence intervals 3.44 to 86.4; P=0.001 for all cases and 17.8 ± 16.2; 95% confidence intervals 3.01 to 105.4; P=0.002 for culture positive cases).
3. Antibiotics started on the first postoperative day rather than on the day of surgery. (odds ratio 13.7 ± 12.9; 95% confidence intervals 2.17 to 90.9; P=0.005 for all cases and 15.9 ± 15.9; 95% confidence intervals 2.27 to 111; P=0.006 for culture positive cases).
4. Ciprofloxacin used rather than ofloxacin (these two represent over 99% of topical antibiotic used during this period) as the post-operative antibiotic (odds ratio 5.26 ± 3.60; 95% confidence intervals 1.41 to 20; P=0.014 for all cases and 7.14 ± 5.61; 95% confidence intervals 1.61 to 32.3; P=0.009 for culture positive cases).
5. The eye not patched after surgery (odds ratio 7.14 ± 5.61; 95% confidence intervals 1.47 to 36.4; P=0.015 for all cases and 9.1 ± 9.1; 95% confidence intervals 1.33 to 62.5; P=0.025 for culture positive cases).
6. Collagen shield soaked in cefazolin (100 mg/ml) and dexamethasone (4 mg/ml) not used after surgery (odds ratio 2.70 ±1.31; 95% confidence intervals 1.06 to 7.14; P=0.037 for all cases; Not significantly (N.S.) different in culture positive cases; P=0.30).

7. The use of a silicone rather than an acrylic intraocular lens (odd ratio 2.63 ± 1.29; P=0.048 for all cases; N.S. in culture positive cases; P=0.36).

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DISCUSSION

Endophthalmitis is a devastating complication, so understanding what we might do to prevent it is of great clinical importance. A study such as this can only find relationships and not causality. We did find potentially important issues. Our most important relationship from this study is the dramatically increased risk associated with capsular breakage or zonular damage at surgery and a wound leak on the first postoperative day. All cases of endophthalmitis were from cases with sutureless, clear corneal incisions with no infections noted in 1,200 cases with superior, scleral incisions. Vitrectomy with cataract surgery has been known to increase the risk of endophthalmitis about four fold[1]; however, our results show a much higher odds ratio (17 to 18 fold for all cases and culture positive cases) than has been reported. Little is known about endophthalmitis as it correlates with capsular breakage in cases with sutureless incisions. The contamination concern from micro-leaks after sutureless incisions makes capsular breakage in this scenario an important consideration.

A recent prospective, randomized study showed that sutureless corneal or limbal incisions can increase the risk of endophthalmitis over scleral incisions[2]. A broken capsule with vitreous exposed to direct bacterial contamination deserves special attention in sutureless, clear corneal cases. Cases of capsular or zonular breakage should probably have a suture placed to minimize the risk of further postoperative contamination. Interestingly, our results suggest sutures increase the endophthalmitis risk. On further evaluation, this association did not stand after a multivariate analysis. This is most likely explained by the fact that sutures were placed in complicated cases which are more likely to have endophthalmitis.

Our greatest association was a leaky wound on the first postoperative day, which supports our overall hypothesis that postoperative contamination of the eye is an important potential problem with sutureless limbal or corneal incisions. With a 44-fold increased risk (21 fold for culture positive cases), such eyes require increased and careful scrutiny. A suture should probably be placed when the leak is discovered in combination with the use of appropriate and frequent topical and possibly oral antibiotics when you consider the risk of endophthalmitis in our series was 1 in 55. These patients deserve frequent contact and a thorough discussion of the signs and symptoms of endophthalmitis. Any sign of increased inflammation during the week should be considered endophthalmitis. Even

though we were aware in early 2001 that the antibiotic used may have great importance in the prevention of endophthalmitis and that wound leakage in sutureless incisions with micro-leaks and micro-contamination probably explained our increased incidence of endophthalmitis, one of our four cases of endophthalmitis in 2001 was secondary to a wound leak and the only case in 2002 was secondary to such a complication.

The use of topical ciprofloxacin postoperatively, not using a collagen shield, not patching and waiting until the first postoperative day to start topical antibiotics were also associated with endophthalmitis. All four factors, we feel, further support our hypothesis about topical or clear cornea micro-leaks and anterior chamber contamination. Ciprofloxacin generally does as good a job as ofloxacin in eliminating superficial contamination[4]; however, our high incidence of endophthalmitis is probably due to micro-leaks after surgery. The main difference between ciprofloxacin and ofloxacin is the fact that ofloxacin penetrates into the anterior chamber about four times more readily than ciprofloxacin[5,6] and therefore, with frequent topical usage, therapeutic levels can more easily be reached in the anterior chamber and potentially eliminate micro-contamination thereby preventing a case of endophthalmitis that otherwise might have occurred. This closely correlates with our protective effect with the collagen shield. As it dissolves, the shields (twelve-hour shields were used) add cefazolin (100 mg/ml) into the eye. All of our positive culture cases were gram positive bacteria, and cefazolin works well on most gram-positive bacteria. The shield may also exert a barrier effect or even help support the wound in the early postoperative period.

Placing a patch was also found to be protective. We feel the patch also has a dual mechanism of action in that a collagen shield without a patch is often blinked out of the eye within 5-10 minutes. The patch ensures that a collagen shield stays in place so that the shield can work. Additionally, the patch itself may also be important in the early postoperative period in keeping the wound closed. Interestingly, our results also showed that starting topical antibiotics the day of surgery significantly prevented endophthalmitis. It would seem that the use of a patch and antibiotics the day of surgery may be mutually exclusive. At our institution, however, when patches are used with collagen shields to keep the shield in place during the early postoperative period, the patch was often placed for four or five hours and then antibiotic drops were placed every one to two hours for the rest of the day. Our study supports this approach.

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Another issue of importance is bacterial resistance. During most of the study period, ciprofloxacin and ofloxacin resistance was not a common problem. Resistance, however, has become an increasingly important issue for these second generation fluoroquinolones[7,8]. Fluoroquinolone resistance was not routinely measured in our series and then only for ciprofloxacin. Only 15 cases were tested for ciprofloxacin resistance and all were listed as sensitive.

As further evidence of the importance of an antibiotic which provides therapeutic intraocular concentrations, largely using ofloxacin, we had only one case of endophthalmitis in 2002 in over 2500 cataract surgeries and this patient had a wound leak after surgery which can potentially defeat all other preventative measures.

The final independent risk associated with endophthalmitis was the use of silicone intraocular lenses. There is no obvious reason why there should be a difference. There is no evidence that silicone, as a material, is more likely to be contaminated or have unusual bacterial adherence. Furthermore, when looking at only culture positive cases this significant difference was not corroborated (P=.361 in our multivariate analysis and .652 in an univariate analysis). This suggests this finding is a statistical anomaly especially considering the Nagaki et al. prospective, randomized, clinical trial[2] which showed no endophthalmitis difference between acrylic and silicone lenses. This issue does deserve further scrutiny.

This endophthalmitis study suggests some steps in regard to endophthalmitis prevention. These considerations are:

1. Patients with a capsular or zonular break with limbal or clear corneal incisions as well as any marginal incision likely to leak probably deserves a suture. If in doubt, a suture should be placed to minimize the risk of contamination.
2. A collagen shield soaked in antibiotic should be considered. Although we have used cefazolin to soak the shield, the antibiotic should probably be changed based upon present-day resistance. New flouroquinolones (gatifloxacin and moxifloxacin) are logical candidates in light of second generation fluoroquinolone resistance[6,7]. Exactly what dosage in relation to epithelial toxicity this might be is the subject of another ongoing study. Furthermore, having the antibiotic from the collagen shield the same as the topical antibiotic to enhance the therapeutic level in the eye, is a reasonable next step from our study

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results. Additionally the collagen shield should be of the shortest duration available. The role of subconjunctival antibiotics can not be analyzed from this study because so few subconjunctival injections were placed with none placed in the cases of endophthalmitis.

3. The eye should possibly be patched, to both help control the wound and keep the collagen shield in place. The patching itself should probably be for approximately four hours based upon our experience; however, the optimal period of time patched versus placing topical antibiotics the first day is not known.
4. Topical antibiotics should be considered frequently the day of surgery, possibly after four hours of patching. With increasing resistance to second generation fluoroquinolones it makes sense to use fourth generation fluoroquinolones every one to two hours on the first surgical day which would further enhance the collagen shield created ocular antibiotic level. Antibiotics should then be used regularly (ie: four times per day) for a week then discontinued to prevent over use and decrease development of bacterial resistance.
5. The antibiotic should be a fluoroquinolone that can achieve adequate aqueous concentrations with excellent minimal inhibitory concentration ratios, fast kill rates and broad spectrum activity against key pathogens (especially gram positive organisms which represent all 20 of our positive cultures).
6. If a wound leak is evident on the first postoperative day then a suture should probably be placed in the wound, and very frequent (every 30 minutes to one hour) topical fluoroquinolone (that readily penetrates into the eye) should be considered. Use of the same oral fluoroquinolone deserves consideration but also requires further scrutiny. The patient should be seen frequently and given a full explanation of the signs and symptoms of endophthalmitis.

Important controversies remain unanswered. Our records did not allow clear differentiation between limbal and corneal incisions, so they were lumped together. We also had no records of antibiotic use prior to surgery other than when the patient arrived at the surgical center. Topical betadine was used in every patient without an iodine allergy. Both topical betadine and antibiotics used days before surgery are important in decreasing the bacterial load at the time of surgery, which may be important in the prevention of endophthalmitis[9,10]. We also could not analyze the impact of switching to topical fluoroquinolones because 99+% were on them, nor could we analyze the impact of subconjunctival antibiotics because this procedure was performed too rarely to analyze.

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Our visual acuity results were good for staphylococcal epidermidis with eight of twelve (67%) patients achieving 20/50 or better vision post-infection. However, of the non-staphylococcal epidermides cases only two of eight (25%) were 20/50 or better and half ended up 20/200 or worse. Our experience also supports those studies[11,12] which show that endophthalmitis is not usually seen on the first postoperative day with only 2 of 27 so detected. On the first postoperative day, the eyes that later developed endophthalmitis, unless there was an incision leak, were uniformly reported as normal. An eye which appears minimally inflamed on the first postoperative day can give a false sense of security and provides little information about whether or not endophthalmitis may follow.

We feel this study gives important clues to the future prevention of endophthalmitis. Our most recent experience of only one case of endophthalmitis in 2002 (over 2500 cataract surgeries) is encouraging. This also suggests that with attention to the antibiotic (type and how used) and wound creation with suturing of marginal wounds, that clear corneal incisions can coexist with a low incidence of endophthalmitis. Other approaches suggested by this study are scleral wounds and sutures with corneal wounds. Which approach might be superior is controversial and can not be answered by this study We hope for a further decrease in endophthalmitis incidence with verification of our findings, completion of additional studies prompted by this work, and potential implementation of other approaches to prophylaxis.

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CLINICAL/EXPERIMENTAL STUDIES

Human Subject Participation in Experimental Investigations: University of Utah IRB approval was obtained for all aspects of this study.

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TABLES

Table 1: Characteristics of control (N=1525), endophthalmitis (N=27) and culture positive (N=20) groups (control represents a 10% sampling of all patients). Raw numbers are in parenthesis.

Category	Control Group	Endophthalmitis Group	Culture Positive
Age (Years)	74.3±14.3	72.2±17.5	71.90±12.4
Gender (Female)	63.2% (964)	56% (15)	60% (12)
Anesthesia (Topical)	85.8% (1308)	92.6% (25)	100% (20)
Incision (Limbal/Corneal) vs. Scleral	91.6% (1397)	100% (27)	100% (20)
Location (Temporal) vs. Superior	91.9% (1401)	100% (27)	100% (20)
Intraocular Lens (Acrylic) vs. Silicone	76.8% (1171)	68% (18)	70% (14)
Collagen Shield Used*	57.5% (867)	37% (10)	45.0% (9)
Eye Patched†	41.7% (636)	11.1% (3)	10.0% (2)
Incision Sutured‡	9.0% (137)	22.2% (6)	25.0% (5)
Capsular or Zonular Breakage§	2.2% (36)	18.5% (5)	25.0% (5)
Pre-operative Antibiotic (Ciprofloxacin) vs. Ofloxacin	57.1% (871)	66.7% (18)	65.0% (13)
Post-operative Antibiotic (Ciprofloxacin) vs. Ofloxacin	47.3% (721)	66.7% (18)	10.0% (2)
Antibiotic Started Day of Surgery vs. Next Day	87.2% (1330)	88.5% (24)	90.0% (18)
Incision Leak on First Post-operative Day‖	0.7% (11)	11.1% (3)	5.0% (1)

* P=0.034 for all endophthalmitis cases (not significant for culture positive cases; P=0.264)

† P=0.001 for all endophthalmitis cases and 0.004 for culture positive cases

‡ P=0.032 for all endophthalmitis cases and 0.013 for culture positive cases

§ P<0.001 for all endophthalmitis cases and for culture positive cases

‖ P=0.002 for all endophthalmitis cases and 0.028 for culture positive cases

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Table 2. A multivariate regression analysis of all factors recorded in the endophthalmitis study. Scleral, and superior incision, as well as retrobulbar anesthesia categories were not included because they predict success perfectly (no cases of endophthalmitis). Culture positive results in parentheses.

	All Endopthalmitis Cases		
Category	**Odds Ratio ± the standard error**	**95% Confidence Intervals**	**P Value**
Age	0.98±.02	0.95 to 1.01	0.28
	(1.00±.02)	(0.96 to 1.05)	(0.92)
Male Gender	1.52±0.67	0.64 to 3.59	0.34
	(1.07±0.56)	(0.38 to 2.99)	(0.90)
Silicone Lens Used	2.63±1.29	1.01 to 6.85	0.048
	(1.71±1.00)	(0.54 to 5.40)	(0.36)
Collagen Shield Not Used	2.70±1.31	1.06 to 7.14	0.037
	(1.72±0.89)	(0.61 to 5.0)	(0.30)
Eye Not Patched	7.14±5.61	1.47 to 36.4	0.015
	9.09±9.09)	(1.33 to 62.5)	(0.025)
Eye Sutured	1.57±1.12	0.39 to 6.33	0.52
	(2.16±1.72)	(0.45 to 10.3)	(0.334)
Zonular or Capsular Complications	17.2±14.2	3.44 to 86.4	0.001
	(17.8±16.2)	(3.01 to 105.4)	(0.002)
Ofloxacin rather than Ciprofloxacin	1.74±1.10	0.50 to 6.01	0.38
used Pre-operatively	(3.60±2.43)	(0.96 to 13.5)	(0.057)
Ciprofloxacin rather than Ofloxacin	5.26±3.60	1.41 to 20.0	0.014
used Post-operatively	(7.14±5.61)	(1.61 to32.3)	(0.009)
Antibiotic not Started Day of Surgery	13.7±12.9	2.17 to 90.9	0.005
	(15.9±15.9)	(2.27 to 111.0)	(0.006)
First Day Incision Leak	44.4±42.3	6.85 to 287.4	<0.001
	(21.4±25.7)	(2.02 to 226.4)	(0.011)

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