Original Article

Are high-efficiency particulate air (HEPA) filters and laminar air flow necessary in operating rooms to control acute post-operative endophthalmitis?

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Purpose: To compare the five-year incidence of acute post-operative endophthalmitis following cataract surgery, between centers with and without laminar air flow and high-efficiency particulate air (HEPA) filters in operating rooms. **Methods:** Retrospective analysis of medical records of patients operated in a single network of a tertiary and four secondary hospitals across north India. Cases of endophthalmitis were identified from the records between January 2013 and June 2018. Protocols and consumables were standardized across all hospitals. The only infrastructural difference being the presence of laminar air flow and high energy particulate air filters in operating rooms of the tertiary center. The type of surgery, along with the demographic and socio-economic details, were captured and analyzed, using z-test for proportions and logistic regression. **Results:** Out of 88,297 cataract surgeries conducted, 36 cases of endophthalmitis were reported. The incidence of endophthalmitis across the network was estimated to be 0.041%, (95% CI: 0.027 to 0.054). There was no statistically significant difference between the incidence of POE at the tertiary (0.042%) and secondary centers (0.039%). Certain risk factors for high endophthalmitis incidence were identified, namely patients undergoing small incision cataract surgery and belonging to lower socio-economic status. However, for both factors the difference was not statistically significant. **Conclusion:** The five-year incidence of acute post-operative endophthalmitis in our network was found comparable to the best reported in literature. Incidence at secondary centers, without laminar air flow and high energy particulate air filters was found comparable to that in the tertiary center having these facilities.

Key words: Cataract surgery, endophthalmitis, high energy particulate air filter, Laminar airflow, resource crunch settings

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Cataract remains a major cause of blindness throughout the world.[1] Cataract surgery is the commonest surgical procedure in developed countries,[2] and surgical numbers are increasing throughout the world.[3] In India alone, more than six million cataract surgeries were performed during 2017-18.[4] With these high numbers, the risk of post-operative adverse events needs to be minimized. Post-operative endophthalmitis (POE) remains an important sight threatening complication in cataract surgery. Hence, asepsis in operating rooms is a priority. Higher risk of POE has been found in patients aged over 80 years,[5] with post capsular rupture.[6] Lower association has been found with male gender[6] Cataract surgery is unique in being of short duration and having a small area of exposure. In ophthalmology, a few practices have modified conventional sterilization and asepsis protocols in high volume cataract surgery settings, and have reported them to be safe, as well as effective in preventing postsurgical endophthalmitis.[7]

Laminar air flow (LAF) regulates airflow with uniform velocity and direction. High efficiency particulate air (HEPA) filters ensure a continuous flow of highly filtered, ultraclean air. This is re-circulated under positive pressure into operating rooms (OR) with surgically generated contaminants being continuously removed.[8] HEPA filters have been shown to reduce fungal air load in hospital wards,[9] and a mobile ultra-clean unidirectional airflow screen has been shown to reduce air contamination for ocular procedures.[10] However, a study in orthopedic operating rooms showed that laminar flow with HEPA filters did not reduce the bacterial load at surgical site.[11] Moreover, there is an argument that once a certain level of air quality is achieved, it is more critical to establish good quality aseptic techniques, instead of improving air quality further with laminar flows.[12] LAFs and HEPA filters significantly add to the cost of cataract surgery. Therefore, it becomes important to evaluate the value of laminar airflow in cataract surgery.

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This study investigated whether the presence of LAF and HEPA filters impacts the incidence of POE. We tested this in our network, which is based on the pyramidal model of service-delivery.[13] We have one city-based tertiary eye care hospital responsible for all complex surgeries, training and research activities; and numerous semi-urban and rural secondary eye care centers, which mainly offer cataract surgery.

Only the tertiary center ORs have been fitted with LAF and HEPA filters. All other standard operating protocols[14-16] for operation room asepsis and instruments sterilization, including re-agents for cleaning, equipment for autoclaving and consumables used, were similar. Results from this study can guide decisions about whether our rural secondary centers, and similar centers in other resource crunch settings, require HEPA filters in ORs.

Methods

Study design and ethical review

This retrospective study was approved by the Institutional Review Board and followed the tenets of Declaration of Helsinki.

Study period, data extraction and linking

Data of all patients operated for cataract from January 2013 to June 2018 at one tertiary and 4 secondary centers, was extracted from integrated hospital management system being used throughout the network. The medical record number was used as a unique identifier of patient records to merge endophthalmitis cases with the master data. To maintain anonymity, no identifiable patient data was included.

Study procedure and participant selection

Data was reviewed for presence of POE. Details of patients who reported with endophthalmitis in the study period were collected from the infection control nurse. POE diagnosis was made based on clinical evaluation of the examining ophthalmologist during postoperative care. Only acute cases, as defined by Yanoff's Ophthalmology,[15] who reported with endophthalmitis before 6 weeks were included. Recent diminution of vision with pain and signs like lid edema, chemosis, increased anterior chamber reaction, hypopyon and vitritis were considered important for raising a suspicion of POE. If fundus view was not clear, then B-scan ultrasound was performed.

All cases of suspected endophthalmitis were reported and investigated as per protocols, including anterior chamber (AC) tap or vitreous biopsy and microbiology testing for KOH and Gram's staining, culture and sensitivity. AC/Vitreous samples were first checked for sample integrity as well as labelling. Gross examination was noted. The sample was inoculated in a sterile area in various solid and liquid media, namely - Blood Agar, Chocolate Agar, Sabouraud Dextrose Agar (SDA), Thioglycolate and Glucose Broth, and then incubated at 37 degree Celsius. KOH and Gram's Staining was done. All media were checked for growths every day, and if there was no growth after 14 days (non-SDA media) and 21 days (SDA media) they were discarded. Intravitreal antibiotics were administered to the patient, without waiting for laboratory and culture results. Vitrectomy with intravitreal antibiotics was performed where indicated. All cases of POE were noted as sentinel events and the hospital infection control committee performed a detailed investigation to take corrective and preventive action within 24 hours.

All secondary center ophthalmologists are trained and instructed to deliver intravitreal injection and collect samples for microbiology. Staining is done there for-KOH and Grams Stain. Media are sent in proper pre-analytical conditions to the main lab in Delhi. Hospital Infection Committee (HIC) either visits physically or communicates online to gather all information regarding patient profile, pre-operative data, intra-operative details, sterilization details, microbiological investigations and follow-up findings. HIC also interrogates all concerned people being involved in management of the patient.

Study setting

Within our hospital network, there is one city-based urban tertiary center and four semi-urban and rural secondary centers, spread across north India. All OTs had split AC without any AHU. In all OTs, it has been made sure that AC flow does not fall directly on OT tables. The tertiary center, unlike the secondary centers, also possessed LAF and HEPA filters in OTs. All cataract procedures were performed either as phacoemulsification (phaco), large-incision extracapsular cataract extraction (ECCE), or manual small-incision cataract surgery (manual SICS).[17] Surgeries were performed by full time faculty ophthalmologists or by surgeons-in-training (SIT) under supervision, at both levels of hospitals. Across the network, around 50% surgeries are provided free of cost to patients coming from outreach camps and primary eye care centers. Rest of the surgeries are performed among walk-in patients who belong to higher socio-economic status groups and pay for their surgeries. Non-paying patients mostly undergo non-phacoemulsification surgery and get operated by both SITs and experienced surgeons, whereas most paying patients receive phacoemulsification and get operated by surgeons other than trainees.

Pre-operative protocol

Across the network, standard operating protocols (SOP) are followed for operation room asepsis and instruments sterilization procedures, including reagents for cleaning and equipment for autoclaving. The hospital's SOPs are in accordance with All India Ophthalmological Society (AIOS) guidelines,[18] as well as the National Accreditation Board of Hospitals and Healthcare Providers (NABH) standards.[19] Culture swabs are taken from operation rooms twice a week and air culture is taken once a month. The swab is taken from OT table, operating microscope, AC duct, suction tip, trolley, scrub area and tap nozzle. Fumigation is done twice per week with disinfectant (D-125) composed of N-alkyl dimethyl benzyl ammonium chloride 2.3% w/v, N –alkyl dimethyl ethylbenzyl ammonium chloride 2.3% w/v, solution, and after every infective case. Air conditioning units are checked routinely once every week and filters are cleaned twice per month. The swab and fumigation procedures are same for all centers. Hand washing is performed according to WHO protocol.[14] Training and audits of hand hygiene are done regularly to ensure best practices. Scrubbing and change of gown and gloves is done post each case. Steam autoclaving is performed for all instruments, gowns, and linen used in surgery. Labels are put on surgical trays displaying date and batch numbers of sterilization. Both chemical and biological indicators are used periodically to check efficacy of sterilization. Chronic

dacryocystitis is common in our population, so syringing is performed in all patients at least one day prior to surgery. Pre-operatively topical antibiotic eye drop (Moxifloxacin) is instilled four times per day, starting one day prior to surgery.

Surgery protocol

Freshly washed clothes and shoe wear are provided to patients. After cleaning of periocular area with betadine, betadine 5% solution is instilled in the eye to be operated, followed by cleaning with dry swab twice before draping. The trolley carrying instruments is prepared as per the surgery. At the end of surgery, an antibiotic drop of 0.5% moxifloxacin is instilled in the eye. Intracameral antibiotic was not used prophylactically in any patient.

Post-surgery follow-up protocol

Follow-ups are conducted on post-operation day one, day seven and day twenty-eight. This is in accordance with AIOS guidelines.[18] Camp patients are made to stay in the hospital overnight following their surgery for the first follow-up. Post-operative instructions are provided by counsellors at the time of discharge. Subsequent follow-up visits are conducted at vision centers or the camp site for non-paying patients to reduce their travel distance and time. To prevent loss to follow-ups, date, time and venue of the next visit are provided to patients in advance. In case the patient is unable to report, the details of the next follow-up camp are provided to them telephonically.

Variables and analysis

A comparison was made between patients from tertiary and secondary centers. The paying category of patients was used as a proxy measure of their socioeconomic status (SES). Patients were stratified based on their socioeconomic status—paying (high SES) or non-paying (low SES)—and the surgical technique—phacoemulsification or non-phacoemulsification (manual small incision surgery)—used in their case. Z-test for discrete variables and a logistic regression were carried out using SPSS version 24 and Microsoft Excel version 16.25. A P value of <0.05 was considered significant.

Results

Demographics

A total of 88,297 cataract extraction surgeries were performed between January 2013 and July 2018. During the study period, 42,418 cataract surgeries were performed at the tertiary center. This accounted for 48% of total cataract surgeries in the network. During the same period, four secondary centers together performed 45,879 cataract surgeries (52% of the total)

Mean age was found to be significantly different in the 2 comparing groups [Table 1]. However, absolute differences between the 2 samples in terms of mean age and proportion of 80 + old patients are not large enough to create a significant difference in the incidence rates of POE. The difference between male-female ratios in two groups [Table 1] was statistically significant. In order to control for these, logistic regression with incidence of POE as the outcome variable and age and sex as two of the explanatory variables was carried out and it was not found to be statistically significant [Table 2].

During the study period, 18 patients at tertiary center and 18 patients at secondary centers, developed POE. Five-year incidence of POE was found to be 0.042%, and 0.039%, for the tertiary and secondary centers, respectively. The difference was not found to be statistically significant (P value = 0.814). There were no cluster infections. The incidence of POE at all locations combined was estimated to be 0.041% (95% CI: 0.027 to 0.054). This included two cases of surgical site infection (SSI) with endophthalmitis. Table 3 shows clinical and microbiological features of cases with POE of the two cohorts.

The difference between the percentages of surgical complications of PCR or zonular dialysis, in two groups was statistically significant [Table 1] but not clinically substantial. Only 2 out of 801 cases (0.25%) in the tertiary centre and 1 out of 702 (0.14%) cases with these complications in the secondary centres developed endophthalmitis [Table 3]. The difference was not statistically significant. After excluding surgical complications, the rates of POE as percentage of the number of surgeries which did not develop these complications were estimated to be 0.038% (16 out of 41,617) in the tertiary centre and 0.037% (17 out of 45,171) in the secondary centres and the difference was not statistically significant. Thus, incidence of surgical complications did not make any difference between two cohorts in our study.

Microbiology

Out of the 36 microbiology samples, 12 underwent AC tap and 24 underwent vitreous tap. *Staphylococcus* species was the commonest gram-positive and *Pseudomonas* was the commonest gram-negative microorganism in samples from both the centers. Table 3 shows comparison between the 2 cohorts.

Surgical technique

Of all surgeries reported during the study period, 38,485 (44%) were phacoemulsification surgeries and the remaining 49,812 (56%) comprised of small incision cataract surgery, (SICS), extra capsular cataract surgery (ECCE) and intra-capsular cataract extraction (ICCE). The majority of the non-phacoemulsification cataract surgeries were SICS (47,227, 94.8%) followed by ECCE (2,493, 5%). ICCE surgeries (92 surgeries) accounted for only 0.2% of the non-phacoemulsification surgeries. Since ECCE and ICCE constituted a minor proportion of non-phacoemulsification surgeries, they were grouped with SICS and analyzed together as non-phacoemulsification surgeries.

Incidence of POE in non-phacoemulsification surgeries (0.046%, 95% CI: 0.027% to 0.065%) was found to be higher than that in phacoemulsification surgeries (0.034%, 95% CI: 0.015% to 0.052%). The difference in rates, however, was not found to be statistically significant (P value = 0.366).

Socio-economic status

Incidence of POE was reported as 0.048% (95% CI: 0.030% to 0.067%) among non-paying patients, and 0.029% (95% CI: 0.011% to 0.047%) among paying ones. This difference was not found to be statistically significant (P value = 0.166). Amongst the non-paying patients, 21.2% underwent phacoemulsification and 78.5% underwent non-phacoemulsification cataract surgeries. These proportions were almost opposite (78.8% phacoemulsification and 21.5% non-phacoemulsification) amongst the paying patients [Fig. 1].

Table 4 shows the incidence of POE in different combinations of paying and non-paying and phacoemulsification and non-phacoemulsification categories. A z-test showed that the

Table 1: Comparison of risk factors between tertiary and secondary centres

	Tertiary Centre	Secondary Centers	*P*
Mean age±SD	62.83±11.12	64.25±9.72	<0.001
Proportion of patients above 80 years old	5.20%	5.50%	0.05
Male:Female Ratio	01:01.1	01:00.9	<0.001
Incidence of posterior capsular rent and zonular dialysis	1.89%	1.53%	<0.001

Table 2: Result of logistic regression (Outcome variable=Incidence of POE)

Variable	Co-efficient	*P*
Type of centre	0.417	0.284
Sex	-0.203	0.547
Age	0.011	0.51
Socio-economic Status (SES)	-0.449	0.433
Type of Surgery	0.055	0.945
Interaction Between SES and types of surgery	0.226	0.809
Constant	-8.624	0

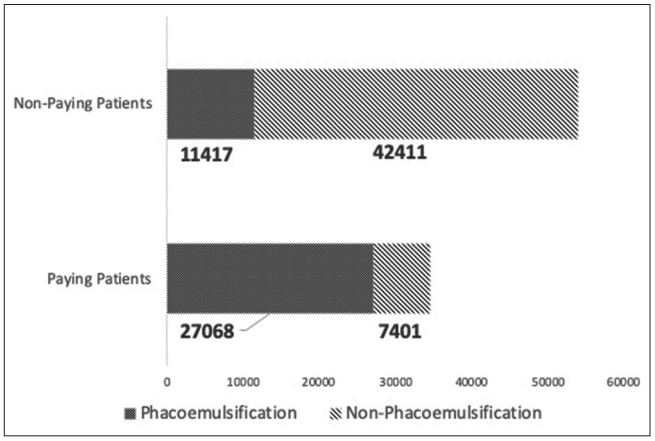

Figure 1: Phacoemulsification and non-phacoemulsification surgeries amongst non-paying and paying patients [original]

difference between incidence of POE in phacoemulsification (n = 38,485) and non-phacoemulsification (n = 49,812) surgeries was not significant (P = 0.366). Similarly, there was no significant difference in the incidence of POE between paying (n = 34,469) and non-paying (n = 53,828) patients (P = 0.166). The difference between the rates of incidence of POE, in phaco and non-phaco surgeries, was similarly not significant amongst paying and non-paying categories, separately (P values = 0.910 and 0.805, respectively).

In order to see the effect of a relevant variable after controlling other variables, a logistic regression was carried out with incidence of POE as the outcome variable and age, sex, type of centres, socio economic class a patient belongs to, types of surgeries and the interaction between socio economic class, and types of surgeries as the explanatory variables [Table 2]. None of the variables mentioned above were found to be significant.

Discussion

Our study is unique in evaluating incidence of POE in hospitals following similar practices and protocols, with and without, HEPA filters and LAF. Similar rates of endophthalmitis are observed after cataract surgery, when surgery was performed in operation rooms at the tertiary eye care center with laminar airflow and HEPA filters, or without these at the secondary care surgical centers. The cost of installation and maintenance is a major limiting factor in resource constrained settings, thus, LAF and HEPA filters were not installed in our secondary centers. Moreover, these are not mandatory as per the present guidelines.[18]

Post-operative endophthalmitis incidence was 0.042% across the network in 88,297 surgical procedures. This was comparable or better than previous studies conducted in India, as well as in the developed world.[7,20-22] These results are in spite of the fact that most of the patients are poor and from rural areas, follow poor hygiene and many even present late, with advanced cataracts that are removed through a large incision.

There is an assumption that ventilation plays a vital role in preventing surgical site infections. LAF are primarily used in operation rooms and are based on the concept of providing a unidirectional stream of clean air over the surgical site, with filtration of air by HEPA filters.[11,23]

Installation of LAF with HEPA filters is expensive, with the need for technical expertise and high maintenance costs,[24,25] adding to the cost of delivery of care. Without proper maintenance, HEPA filters may not be helpful.[26] Therefore, it is important to have clear evidence of its' utility to mandate it's use in cataract surgery. Existing literature lacks evidence and some researchers even question it's need.[11,27,28] A recent systematic review, undertaken for the last three decades, compared ventilation by laminar air flow with conventional ventilation, and found LAF not effective in reducing the incidence of surgical site infections (SSI) in hip and knee surgeries.[29] A study similar to ours, found no difference in SSI in hospitals with, and without, laminar flow for arthroscopy.[30] As most evidence based literature pertaining to LAF is from realms outside of ophthalmology, our study on a large number of patients is not only unique, but also becomes extremely relevant for this field.

Some practices are accepted as convention without clear cut evidence as it is not always possible to carry out randomized trials. The practice of changing gloves between every cataract case was shown to be unnecessary for prevention of POE by Ravindran *et al.*[7] In their study protocol, a change of gloves was recommended after every 10 cases, and the incidence of POE was shown to not be affected. Similarly, we believe that laminar air flow and HEPA filters recommended in ophthalmic operating rooms,[31] is another such convention, without clear evidence. This is highlighted further in the ESCRS multi-centric

Table 3: Clinical and microbiological features of cases with POE

	Tertiary Centre	Secondary Centres
Posterior capsular rent	2	1
Systemic conditions	Diabetes 6	Diabetes 6, HIV 3
Endophthalmitis within 10 days of surgery	11	12
Hypopyon at presentation	8	10
Delay in reporting (more than 2 days after onset of symptoms)	2	5
Intravitreal given on the day of reporting	18	18
Core vitrectomy done	12	10
Poor recovery	3 patients, 1 prethisical, 1 evisceration, 1 underwent TPK with failed graft	4 patients, 1 prephthisical, 1 striate keratitis with corneal edema, 1 with patch graft and poor visual recovery, 1 poor visual recovery with pale disc
Lost to follow up within 1 week of treatment	1	3
Microbiology		
Bacterial	8	6
Gram positive	5	4
Gram negative	3	2
Fungal	1	1
No growth	9	11

Table 4: Incidence of POE in different combinations of paying and non-paying and phacoemulsification and non-phacoemulsification categories

	Phacoemulsification (Phaco)	Non-Phacoemulsification (Non-Phaco)	*P* (z-test to compare phaco and non-phaco surgeries)	Total Incidence
Paying	0.03%	0.03%	0.91	0.03%
Non-paying	0.04%	0.05%	0.805	0.05%
Total	0.03%	0.05%	0.366	0.04%

study, where there was no definitive conclusion regarding laminar air flow.[32]

Although not statistically significant, incidence of POE was more in non- phacoemulsification surgeries and in non-paying surgery group. The higher incidence in non-phaco was in accordance with the study conducted by Ravindran *et al*.[7] However, the authors did not find any significant difference with socio-economic status. Nevertheless, a previous study from south India reported higher infection rates associated with lower socio-economic status,[33] linking the same to residential conditions and health education. However, we did not find any significant effect either of the type of surgery, or of the socio-economic status, on the incidence of POE. Even the interaction between surgery type and socio-economic status did not suggest anything different.

A limitation of our study is that it is based on retrospective data and there is a possibility that despite the best of our efforts and protocols for follow-up, a few patients with POE might not have reported. Although all our ORs follow the NABH recommendations,[17] they may have differed slightly when it comes to certain factors like ceiling height, positioning of personnel and/or equipment (heating units and lighting) within the area of LAF, number of people, activity in the ORs and positioning of the instruments table in the OR. We believe that our results may still be generalizable to centers adhering to standard protocols and recommendations.

Conclusion

In our study, we found when standardized protocols were followed, it was not necessary to have LAF and HEPA filters to control incidence of endophthalmitis. Thus, it raises the question of necessity of LAF and HEPA filters in ophthalmic operating rooms, especially in resource crunch settings.

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Conflicts of interest

There are no conflicts of interest.

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