

# Impact of a laminar air flow portable device on post-intravitreal injection endophthalmitis rate

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## ABSTRACT

Intravitreal injections (IVIs) are the most common outpatient procedure worldwide, yet no consensus exists regarding their optimal setting. This study analysed 101 976 IVIs performed between 2017 and 2023, comparing endophthalmitis rates before and after introducing a mobile laminar air flow (LAF) device in a clean room. The incidence of endophthalmitis decreased from 0.033% to 0.013%, a 63.2% risk reduction (Odds Ratio=0.368, p=0.04). These findings suggest that mobile LAF enhances air quality and reduces infection risk, offering a cost-effective, efficient alternative to operating theatres for IVIs.

## INTRODUCTION

Intravitreal injections (IVIs) are the most common outpatient procedure globally, with approximately 6 million performed in the USA in 2016 alone.<sup>1</sup>

No consensus exists on whether IVIs should be conducted in operating theatres (OTs) or office-based clean rooms, and major retina organisation guidelines lack specifications regarding air quality requirements.<sup>2,3</sup>

This study evaluates the impact of a mobile laminar airflow (LAF) device<sup>4</sup> in a dedicated clean-room IVI setting on post-IVI endophthalmitis rates.

## METHODS

In this interventional case series, we reviewed clinical records and electronic logbooks of IVI claims at the Luigi Sacco Hospital in Milan, Italy, and collected the number of IVIs and post-IVI endophthalmitis before and after the introduction of a mobile LAF device.

IVIs are performed in dedicated clean rooms by trained ophthalmologists with standard sterile technique. The injector wears a standard surgical mask, a non-woven fabric coat and sterile surgical gloves.

After consent and checks, anaesthetic eyedrops are applied and asepsis is performed using 5% povidone-iodine on the ocular surface, followed immediately by the application of 10% povidone-iodine to the periocular skin. A contact time of 3 min is observed to ensure adequate antimicrobial effect.

Drape and speculum are placed and the IVI is performed. A drop of preservative-free netilmicin and dexamethasone 3 mg/mL+1 mg/mL is applied.

The Operio Mobile Sterile Air Unit (Toul Meditech, Sweden) is a CE-marked mobile LAF device capable of reducing airborne particles up to ISO 5 standards. The Operio was introduced to the clean

rooms on 1 March 2020, providing unidirectional LAF to the surgical tray and eye undergoing treatment. During and after the COVID-19 pandemic, no further modifications to the procedure or the setting were adopted, except for the introduction of the LAF device. Patients began wearing surgical masks only during the COVID-19 pandemic. However, they were advised to remove the mask before the surgical procedure and to wear it again immediately afterward. The use of surgical masks by patients was discontinued once the COVID-19 pandemic had officially ended.

All cases of post-IVI endophthalmitis underwent prompt 25G Pars Plana Vitrectomy and intravitreal antibiotics injection (vancomycin 10 mg/mL and amikacin 5 mg/mL).<sup>5</sup> In all cases, a dry vitreal biopsy was obtained for microbiological cultures and antibiogram.

Patients with a confirmed allergy to povidone-iodine were excluded from the analysis; specifically, three patients who received IVs under alternative antiseptics with 0.1% aqueous chlorhexidine were not included in the study cohort.

The cumulative incidence rates and the Odds Ratio (OR) of post-IVI endophthalmitis with and without LAF device were calculated. Covariates in the OR binomial model included age, gender and the number of previous IVIs received. A Fisher's exact test was used to compare the proportion of culture-positive endophthalmitis cases in the two groups. A p<0.05 was considered statistically significant. All analyses were conducted using R version 4.4.0 (R Project for Statistical Computing, Austria).

## RESULTS

A total of 101 976 IVIs received by 8395 patients between 1 July 2017 and 31 December 2023 were analysed. Before and after the introduction of the LAF device, 33 478 and 68 498 IVIs were administered, respectively.

Information on the drug delivered was available for 69 010 IVIs, including 28 884 bevacizumab (41.8%), 22 085 aflibercept (32%), 16 477 ranibizumab (23.9%), 865 dexamethasone IV implants (1.25%), 686 brolocizumab (0.99%) and 13 fluocinolone acetonide implants (0.02%).

There were 20 post-IVI endophthalmitis cases in 19 patients, including 1 bilateral, non-simultaneous case. The most common pathogen isolated from the vitreous cultures was *Staphylococcus epidermidis* (n=7, 35%). In 50% of cases, cultures were negative (n=10). The case details are presented in [table 1](#).



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**Table 1** Clinical details of endophthalmitis cases

Case	Age	Gender	Indication	IVI drug	Days post-IVI	Lab results
1	60s	M	PCV	Bevacizumab	3	<i>Staphylococcus saprophyticus</i>
2	70s	M	RVO	Dexamethasone implant	3	<i>Staphylococcus epidermidis</i>
3	60s	M	DR	Ranibizumab	3	Lab Negative
4	60s	M	DR	Aflibercept	5	Lab Negative
5	80s	M	RVO	Dexamethasone implant	2	<i>Staphylococcus aureus</i>
6	60s	F	nAMD	Ranibizumab	6	Lab Negative
7	70s	F	nAMD	Bevacizumab	6	<i>Staphylococcus epidermidis</i>
8	80s	M	DR	Dexamethasone implant	7	Lab Negative
9	70s	F	nAMD	Ranibizumab	3	Lab Negative
10	60s	F	DR	Aflibercept	2	<i>Streptococcus mitis/oralis</i>
11	60s	F	nAMD	Aflibercept	7	Lab negative
12	90s	F	nAMD	Bevacizumab	3	Lab negative
13	70s	M	nAMD	Aflibercept	5	<i>Staphylococcus epidermidis</i>
14	90s	M	nAMD	Bevacizumab	42	Lab negative
15	70s	F	nAMD	Aflibercept	4	<i>Staphylococcus epidermidis</i>
16	60s	F	nAMD	Aflibercept	3	<i>Staphylococcus epidermidis</i>
17	70s	M	nAMD	Ranibizumab	4	Lab negative
18	80s	M	PCV	Bevacizumab	4	<i>Staphylococcus epidermidis</i>
19	70s	M	nAMD	Bevacizumab	4	Lab negative
20	70s	F	nAMD	Bevacizumab	4	<i>Staphylococcus epidermidis</i>

DR, diabetic retinopathy; IVI, intravitreal injection; nAMD, neovascular age-related macular degeneration; PCV, polypoidal choroidal vasculopathy; RVO, retinal vein occlusion.

The global incidence of post-IVI endophthalmitis was 0.02% (95% CI [0.012% to 0.03%]) per IVI, which corresponded to an incidence of 0.238% (95% CI [0.145% to 0.367%]) per patient.

A total of 11 and 9 post-IVI endophthalmitis cases were recorded before and after the introduction of the LAF device, respectively. The incidence of post-IVI endophthalmitis before was 0.033% (95% CI [0.016% to 0.059%]), while the incidence of post-IVI endophthalmitis after was 0.013% (95% CI [0.006% to 0.025%]). This corresponded to a 63.2% reduction in the odds of developing a post-IVI endophthalmitis with the use of the LAF device (OR=0.368, 95% CI 0.14 to 0.966,  $p=0.04$ ).

No significant difference was observed in the rate of culture-negative endophthalmitis (5/11 cases pre-LAF and 5/9 post-LAF introduction, OR=0.68, 95% CI 0.08 to 5.36),  $p=1.00$ . In the bilateral, non-simultaneous case (cases 3 and 4 in table 1), the two episodes occurred 3 years apart. The onset of symptoms was 3 days after the IV in the first eye and 5 days after in the second. In both instances, the presentation included hypopyon, dense vitreous opacities and diffuse retinal haemorrhages—findings confirmed intraoperatively during vitrectomy. Although both cases were culture-negative, the clinical features were highly suggestive of infectious endophthalmitis rather than Toxic Anterior Segment Syndrome.<sup>6</sup>

## DISCUSSION

In this study, the introduction of a mobile LAF device significantly reduced the odds of developing post-IVI endophthalmitis performed in a dedicated clean room at a single tertiary referral centre with high-volume IVI clinics.

IVIs now surpass cataract surgery in annual post-procedural endophthalmitis cases.<sup>7</sup> While IVI administration is relatively standardised, some countries require OTs, whereas most IVIs worldwide occur in clean rooms or office settings. A key OT feature is stringent air quality control, including LAF systems, which replaced conventional ventilation after a pivotal 1974 randomised trial.<sup>8</sup> LAF systems provide unidirectional, bacteria-free airflow, reducing surgical site infections.

Several studies have assessed post-IVI endophthalmitis rates across different settings. A meta-analysis of over one million IVIs reported a 0.03% infection rate in office settings and 0.02% in OTs, with no significant difference.<sup>9</sup> Similarly, a French study analysing 316 576 IVIs found no difference in infection rate between IVIs performed with or without filtration airflow in clean rooms, reporting an overall rate of 0.021%.<sup>10</sup>

To our knowledge, this is the first large monocentric report of post-IVI endophthalmitis incidence with and without a mobile LAF device in a clean room setting. The endophthalmitis rate of 0.033% prior to the implementation of the LAF device aligns with what was reported by Dossarps *et al.*<sup>10</sup> The mobile LAF contributed to reducing the post-IVI endophthalmitis rate to 0.013%, with a 63.2% decrease in the odds of developing a post-procedural ocular infection. Our findings suggest that the mobile LAF device could be ideal in non-OT settings to enhance local air quality and reduce the incidence of post-IVI endophthalmitis. This approach could be especially beneficial in countries where IVIs are not allowed in an in-office setting.

The use of a dedicated clean room with mobile LAF may increase IVI capacity while reducing procedural costs associated with OT settings without raising infection risk. Future studies could evaluate similar devices in office-based settings.

Limitations of this study are inherent to its retrospective nature. However, large prospective studies comparing different IVI settings are not feasible due to the extremely low prevalence of post-IVI complications, especially endophthalmitis, which would require very large sample sizes to demonstrate significant differences between treatment protocols.<sup>9 10</sup> As a further limitation, data regarding the identity of the clinician performing each IV were not recorded in our registry and were therefore unavailable for analysis; this represents a limitation of the study, as injector-related variables could not be assessed. Conversely, the main strength of our report is the inclusion of over 100 000 IVIs from a single referral centre, all performed under uniform conditions, with the only variable being the use of the mobile LAF device.

In conclusion, this study demonstrated a 63.2% reduction in post-IVI endophthalmitis risk with mobile LAF use over more than 100 000 IVIs. While endophthalmitis remains a rare IVI complication, the global increase in IVI treatments underscores the need for infection-minimising measures such as mobile LAF devices, ensuring patient safety while improving procedural efficiency and accessibility.

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**Ethics approval** This study involved human participants; however, the local Ethics Committee stated that formal approval was not required due to the retrospective nature of the study and the impossibility of identifying individual patients from the data. This study adhered to the tenets of the Declaration of Helsinki and informed consent was waived by the local Institutional Review Board.

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