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## ORIGINAL ARTICLE

# Safeair injection cabinet in the semi-sterile room: Safety profile and early results of new design intravitreal injection room with double security

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### Abstract

**Purpose:** The purpose of the study was to determine the rate of endophthalmitis in intravitreal injection (IVI) cases performed in the IVI cabinet inside the semi-sterile room developed in accordance with the operating room conditions and to evaluate the results of the performance tests of the IVI cabinet.

**Methods:** The number of IVIs, the type of drug administered intravitreally, ocular pathologies leading to IVI, possible endophthalmitis occurrence, and demographic characteristics of the patients were retrospectively analyzed between February 2023 and March 2024 in the IVI cabinet inside the semi-sterile IVI room in the Ophthalmology Department of Giresun Training and Research Hospital.

**Results:** A total of 1082 patients were included in the study. A total of 4380 IVIs were performed. The drugs used in IVIs were Bevacizumab in 2776 (63.4%), Ranibizumab in 697 (15.9%), Aflibercept in 678 (15.5%), and Dexamethasone implant in 229 (5.2%). The indication diagnoses for IVI were diabetic macular edema in 573 (53%) patients, exudative age-related macular degeneration in 292 (27%) patients, retinal vascular occlusion in 163 (15%) patients, non-infectious uveitis in 39 (3.6%) patients, and myopic choroidal neovascularization in 15 (1.4%) patients. None (0%) of the IVIs administered to the patients in the IVI cabinet in a semi-sterile room developed endophthalmitis.

**Conclusion:** IVIs can be administered effectively and safely in the IVI cabinet system in a semi-sterile chamber.

**Keywords:** Double security; endophthalmitis; injection cabinet; intravitreal injection; intravitreal injection room.

Intravitreal injections (IVIs) are now routinely used in many ophthalmology clinics for the treatment of diabetic macular edema, age-related neovascular macular degeneration, retinal vein occlusion, myopic choroidal neovascularization, and macular edema secondary to

non-infectious uveitis.<sup>[1-5]</sup> Although IVIs are a common surgical procedure, they can cause serious complications.<sup>[6]</sup> The most devastating complication, although less frequent, is endophthalmitis, which can also adversely affect visual function.<sup>[7]</sup>



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When IVI practice settings are analyzed, there are differences between countries in terms of regulations and guidelines. In many countries, IVI are administered in an ambulatory, operating room, or office setting outside the hospital, whereas in Italy, intravitreal anti-vascular endothelial growth factor (VEGF) agents are administered only by ophthalmologists in specialized hospitals designated by the regional government and not outside the hospital.<sup>[8]</sup>

In our country, the frequency of IVIs in cabins with sterile air circulation has increased due to the increasing use of IVI treatment, the inadequacy of the existing sterile operating room facilities compared to the number of patients, and the high cost of IVI treatment.

In this study, we aimed to present the design of the IVI cabinet in a semi-sterile environment similar to the operating room environment to provide more practical and safer IVIs in our clinic. In addition, this study evaluates the endophthalmitis rate of IVI application in the IVI cabinet and the results of IVI cabinet performance tests.

## Materials and Methods

The study was conducted in accordance with the Declaration of Helsinki. Approval for this study was obtained from the Local Ethics Committee of Giresun Education and Research Hospital (IRB 28/03/2024-03). Informed consent was obtained from all participants before inclusion in the study. In February 2023, IVIs were started to be administered in a semi-sterile room with sterile airflow in the Ophthalmology Clinic of Giresun Training and Research Hospital. Between February 1, 2023, and March 15, 2024, all IVIs performed in the Ophthalmology Clinic of Giresun Training and Research Hospital were retrospectively analyzed using the hospital information recording system. Demographic characteristics of the patients and current IVI indication diagnoses were determined using statistical analysis systems. The aim of this study was to determine the number of endophthalmitis cases that developed after IVI performed in a semi-sterile room with sterile airflow.

## Injection Method

IVIs were administered by ophthalmologists in an IVI cabinet in a semi-sterile room after the approval of the Giresun Training and Research Hospital Infection Control Committee.

IVIs were used for the treatment of diseases such as diabetic macular edema, age-related neovascular macular degeneration, retinal vein occlusion, myopic choroidal neovascularization, and non-infectious uveitis.

The drugs used for intravitreal injection were Ranibizumab 0.5 mg/0.05 mL (Lucentis®, Genentech Inc., South San Francisco, CA, USA, and Novartis AG, Basel, Switzerland), Aflibercept 2 mg/0.05 mL (Eylea®; Regeneron Pharmaceutical Inc., Tarrytown, NY, USA, and Bayer, Basel, Switzerland), 1.25 mg/0.05 mL Bevacizumab (Avastin®; Genentech USA, Inc.), and Dexamethasone implant (Ozurdex®, Allergan Inc., Irvine, CA, USA).

Intravitreal Bevacizumab injections were administered in the IVI cabinet by filling multiple syringes from a single vial in accordance with sterile conditions. Intravitreal Aflibercept injections were administered from a single vial into one syringe. Intravitreal Ranibizumab injection was administered as a ready-to-use syringe (Pre-filled Syringe) and intravitreal dexamethasone implant was administered as a pre-prepared intravitreal implant form.

The room where IVI injections are administered consists of two sections: anterior and posterior. Patient preparation is performed in the front room.

Sterile surgical clothing, surgical masks, surgical caps, and overshoes were applied to the patients before IVI. The prepared patients were taken to the room in the back section and placed in the cabin with their heads inside the cabin. Patients were topically anesthetized with proparacaine hydrochloride eye drops before IVI. The treating ophthalmologists used sterile surgical clothes, a surgical mask, a surgical cap, a sterile drape, and overshoes. Hand sterilization was performed using povidone-iodine before putting on sterile gloves. Periocular surfaces and eyelids were disinfected with a 10% povidone-iodine solution. A sterile drape was placed, and a speculum was placed on the eyelid. A 5% povidone-iodine solution was applied to the conjunctiva and fornices and washed with a sterile isotonic solution after waiting for 3 min. An intravitreal agent was administered from the superior temporal area at a distance of 3.5 or 4 mm from the limbus using a 30 gauge needle, depending on the patient's lens status. Pressure was applied with a cotton rod to prevent vitreous leakage. After injection, light sensation was evaluated for possible arterial occlusion. The eyes were closed with an eye patch for 2–3 h. Patients were prescribed moxifloxacin 0.05% drops to be administered 5 times a day for 5 days.

## Cabin Features

The cabinet is 180 × 180 × 210 cm in size, completely closed on three sides, with an opening in the front for

patient access. The IVI cabin system provides a sterile operating room environment by providing recirculated laminar airflow. The air needed for the cabin environment is filtered from the room environment with the help of fans, and this air is supplied to the cabin environment vertically through 4 H13 HEPA class filters through the laminar flow unit. The sterile air filter system in the cabin has been tested using TS EN ISO 14648-1, TS EN ISO 14648-2, TS EN ISO 14648-3, IEST-RP-CC006.3, IEST-RP-CC034.4, Eudralex volume 4, and Food and Drug Administration Current Good Manufacturing Practice reference tests.

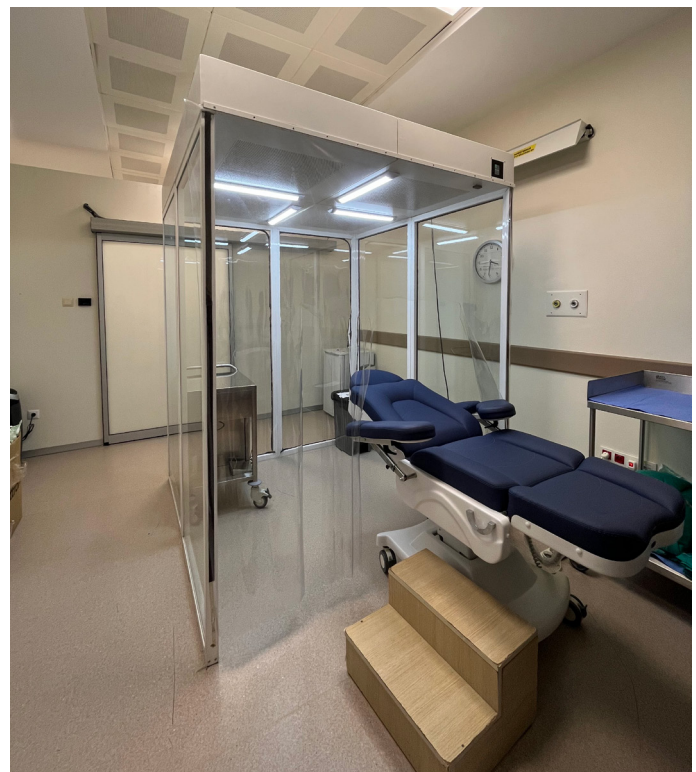
The HEPA filters (Safeair) in the sterile air filter system provide a nominal airflow of 600 m<sup>3</sup>/h with a particle retention efficiency of 99.95%. With 452 air changes, it meets the ISO Class 8 criteria of at least 20 air changes per hour. The existing 4 HEPA and ULPA filters (Safeair) meet TS EN ISO 14648-3 criteria with a leakage level of <0.01. Clean area particle measurements were 211.9 and 423.8 at 0.5 µm/m<sup>3</sup> in two areas, respectively, meeting the ISO 5 class criteria of 3,520/m<sup>3</sup> particles.<sup>[9]</sup> The clean area maintains an average temperature of 21.6°C and 40% humidity. The existing Rosh LED bulb provides 99.99% sterilization with ultraviolet (UV)-C 13. The fan system emits 67 dbA at a maximum speed of 2100 rpm.

There are three UVPOWER sterile air filter systems in the room. The UVPOWER sterile air filter system provides six-stage filtration and sterilization. These are: Coarse dust filter, activated carbon filter, hepa filter, UV light (photocatalyst), titanium dioxide filter, and ionizer. The HEPA filters in the UV POWER provide four air changes per hour in a 50 m<sup>2</sup> room. The HEPA filters in the UVPOWER sterile air filter system prevent at least 99.97% of particles as small as 0.3 µm from being carried in the air.

It is recognized as "EN 1822:2009" in European norms and conditions. Approximately 95% of the UV energy emitted from the existing UV-C lamp is in the 254-nanometer mercury resonance line. This wavelength is in the region of maximum microorganism-destroying activity. The inside and outside views of the IVI chamber and IVI cabinet are shown in Figures 1-3.

### Statistical Analysis

Statistical analyses were performed using Statistical Package for the Social Sciences 26.0 for Windows (IBM Corp., Armonk, NY, USA). Descriptive statistics were used in our study, with quantitative variables reported as mean and standard deviation and qualitative variables reported as percentages.



**Fig. 1.** View of the injection room.



**Fig. 2.** Outside view of the injection cabinet.



**Fig. 3.** Inside view of the injection cabinet.

**Results**

A total of 1082 patients were included in the study. The mean age of the participants was 66±11.9 years for females and 67±12.2 years for males (p=0.896). There was no statistically significant difference in age between male and female participants. Of the patients, 568 (52.5%) were female and 514 (47.5%) were male. The indication diagnoses for IVI were diabetic macular edema in 573 (53%) patients, exudative age-related macular degeneration in 292 (27%) patients, retinal vascular occlusion in 163 (15%) patients, non-infectious uveitis in 39 (3.6%) patients, and myopic choroidal neovascularization in 15 (1.4%) patients. A total of 4380 IVIs were performed. IVI was performed in 3540 (80.8%) patients in one eye and 840 (19.2%) patients in both eyes (Table 1). Of the IVIs, 2776 (63.4%) were Bevacizumab, 697 (15.9%) were Ranibizumab, 678 (15.5%) were Aflibercept, and 229 (5.2%) were Dexamethasone (Table 2). Patients were followed up on the 1<sup>st</sup> day, 1<sup>st</sup> week, 1<sup>st</sup> month after IVI (when they came for a repeat injection or the first month of intravitreal dexamethasone), and if an intravitreal dexamethasone implant was applied, at the 2<sup>nd</sup> month of the IVI.

**Table 1.** Demographic characteristics of the patients

	n (%)
Gender	
Female/Male	568 (52.5)/51 (47.5)
Age	
Female/Male	67±12.2/66±11.9
Eye	
Unilateral/Bilateral	872 (80.6)/210 (19.4)
Diagnosis	
Diabetic retinopathy	573 (53)
Age related macular degeneration	292 (27)
Retinal vascular occlusion	163 (15)
Non-infectious uveitis	39 (3.6)
Myopic choroidal neovascularization	15 (1.4)

IVI: Intravitreal injections. n Patient=1082; n IVI=4380.

**Table 2.** Distribution of intravitreal-administered drugs

Drugs	Number of injections (%)
Bevacizumab	2776 (63.4)
Ranibizumab	697 (15.9)
Aflibercept	678 (15.5)
Dexamethasone	229 (5.2)

None (0%) of the IVIs administered to the patients in the IVI cabinet in a semi-sterile room developed endophthalmitis.

**Discussion**

IVIs have recently been widely used in the treatment of various macular diseases, such as diabetic retinopathy, age-related neovascular macular degeneration, retinal vein occlusion, myopic choroidal neovascularization, and non-infectious uveitis.<sup>[1-5]</sup> In our country, according to the Social Security Institution Health Implementation Communiqué, the intravitreal Bevacizumab loading dose must be administered in 3 consecutive doses (1.25 mg/0.05 mL) with an interval of 4–6 weeks in patients for whom IVI treatment is planned. After loading therapy, intravitreal Aflibercept, Ranibizumab, and Dexamethasone can be administered. The bevacizumab loading dose is not required only for the treatment of visual impairment due to choroidal neovascularization secondary to pathological myopia.<sup>[10]</sup> Bevacizumab injections are administered by filling a single vial into multiple syringes in accordance with sterile conditions. Aflibercept is administered from a single vial into a syringe as a single fill, and a ready-to-use syringe form is not available in Türkiye. Ranibizumab is administered

as a ready-to-use syringe (PFS). The rubber stopper in the ready-to-use syringe form prevents the extraction of non-sterile air and reduces the risk of contamination. The available Luer lock system reduces leakage and contamination. The piston rod that moves into the reservoir cannot be retracted, preventing sterility deterioration. It reduces the risk of contamination and sterility deterioration that occurs during the manual filling of the syringe from the vial.<sup>[11]</sup> The ready-to-use syringe form has a 2–5 times lower endophthalmitis rate compared to the vial form.<sup>[12]</sup> For intravitreal dexamethasone, a pre-prepared intravitreal implant form was used.

IVI is now widely used in ophthalmology clinics but can cause complications such as IOP elevation, rhegmatogenous retinal detachment, intraocular inflammation, subconjunctival hemorrhage, and endophthalmitis.<sup>[6]</sup> A meta-analysis evaluating the safety of IVI with anti-VEGF agents in office and operating room settings found that ocular perioperative complications, including posterior vitreous detachment, iatrogenic/traumatic cataracts, retinal detachment, and retinal tears, were mostly due to inappropriate injection techniques. The low incidence rates of these complications (0–0.67%) were independent of the setting. Moreover, the injection setting did not affect systemic safety, and no serious systemic perioperative complications were reported in a study analysis of a total of 1,275,815 injections.<sup>[13]</sup>

Endophthalmitis is a serious and devastating complication after IVI, albeit at a low rate. In a meta-analysis of the rate of endophthalmitis after IVI, the percentage of endophthalmitis was reported to be 0.061.<sup>[14]</sup> In a 17-month retrospective study, 23 (0.083%) cases of endophthalmitis were detected after 27,736 injections.<sup>[15]</sup> At the Mayo Clinic ophthalmology department in Rochester, Minnesota, there were 3 cases of endophthalmitis after 3,875 IVIs administered between January 2005 and October 2007; the rate was 0.077%.<sup>[16]</sup> A retrospective study of 1,095,305 IVIs administered between 2005 and 2016 reported 380 cases of endophthalmitis.<sup>[17]</sup> An evaluation of a prospective comparison of age-related macular degeneration treatment trials (CATT) with 18,509 data based on injections in the office showed an endophthalmitis rate of approximately 0.06%.<sup>[18]</sup>

A study was conducted on the application environment and complications of intravitreal anti-VEGF therapy between 2006 and 2022. A literature review was conducted, and a questionnaire was sent through e-mail to ophthalmologists specializing in this field from 23

countries on five continents to obtain information about the environment for intravitreal anti-VEGF administration. In all 23 countries, including Australia, France, and Japan, IVI was performed in outpatient operating rooms or clean rooms. Fourteen of the 23 countries, including Germany and Belgium, do not allow IVI in the office setting, while nine countries, including France and Australia, allow IVI in the office setting. Of the 23 countries in the study, only Italy does not allow out-of-hospital intravitreal anti-VEGF use.<sup>[8]</sup>

Many studies have examined the relationship between the setting of IVI and the incidence of endophthalmitis. Moshfeghi et al.<sup>[19]</sup> retrospectively analyzed 60,322 IVI cases performed in an office setting and found endophthalmitis in only 12 cases (0.02%). Pilli et al.<sup>[20]</sup> retrospectively analyzed IVI cases performed in the office setting between 2005 and 2007 and reported an endophthalmitis rate of 0.029%.

In a retrospective study of 134,701 IVIs performed in the operating room between 2003 and 2016 in three centers, endophthalmitis was reported in only 10 cases (0.0074%).<sup>[21]</sup> In a retrospective study conducted in two eye hospitals in Sweden between 2004 and 2012, endophthalmitis was reported in 3 cases (0.0075%) of a total of 40,011 IVIs performed under sterile operating room conditions.<sup>[22]</sup> In another study, a total of 11,710 IVIs were retrospectively analyzed from January 2009 to December 2011, and no significant difference was found in the incidence of endophthalmitis between the operating room and office environment.<sup>[23]</sup> In a meta-analysis study, 31 studies with 1,275,815 IVIs were analyzed, and no difference was found between endophthalmitis rates after IVIs performed in office and operating room settings.<sup>[13]</sup> In this study, no endophthalmitis was reported after 4380 IVIs performed in a 1 year period, and the findings were consistent with the literature.

In our country, HEPA-filtered ventilation systems are used to create a sterile field. The airflow in operating rooms should be from sterile to free space (positive pressure airflow), and operations with a high risk of surgical site infection should be performed in rooms with laminar airflow. Ventilation systems should provide at least 15 filtered air exchanges per hour, of which at least 3 (20%) should be with fresh air. Performance tests such as HEPA filter compatibility (leak test), air flow and air velocity measurement, detection of pressure differences and airflow directions between areas, measurement of system efficiency (re-cleaning), and particle measurement are applied.<sup>[9]</sup>

Clean area particle measurements were 211.9 and 423.8 at 0.5  $\mu\text{m}/\text{m}^3$  in two areas, respectively, and were found to comply with ISO class 5 criteria. Thus, it meets all the criteria required for the operating room environment conditions in our country.

In one study, IVI was applied in the cabin system developed to apply IVI by creating a positive pressure laminar air flow with a G4 and H14 double filtration system using room air without the need for a different air conditioning system. With the side panel available in the cabin system, clean air is discharged from the sides and bottom of the cabin so that both the room in which the cabin is located and the air in the cabin are continuously filtered, and there is no open area in front as it creates positive air pressure. In this study, no cases of endophthalmitis were reported in 7238 IVIs.<sup>[24]</sup>

A 0% endophthalmitis rate has been reported after more than 10,000 IVIs using the Arcsterile cabinet system. In the Arcsterile cabinet system, laminar airflow is provided by filters on the sides, and there is a completely open side at the front.<sup>[25]</sup> In a study conducted in Spain, cases of intravitreal dexamethasone implantation using the operating room and Arcsterile cabinet were compared in terms of endophthalmitis, and it was reported that 0 cases of endophthalmitis were reported after 454 dexamethasone implants performed in the operating room, and no cases of endophthalmitis were reported in 1054 cases of intravitreal dexamethasone implantation performed in the Arcsterile cabinet, and it was stated that the cabinet system can be used safely.<sup>[26]</sup>

In the literature, it has been reported that the rate of endophthalmitis in the provision of anti-VEGF drugs in pre-filled forms is almost half of the rate recorded in drug administration where the syringe is filled from a vial.<sup>[27,28]</sup> It has been suggested that the use of pre-filled syringes eliminates the time required to fill a syringe from a vial, thus reducing the risk of contamination. In the present study, we believe that the absence of endophthalmitis despite the use of bevacizumab drawn from one vial into multiple syringes may be due to strict adherence to sterility rules and the purity of the air obtained in the cabin.

The most important limitations of this study are the retrospective nature of the study, the fact that the information was obtained using only the hospital record system, and the relatively small number of patients. In addition, the lack of a group to compare the injection cabinet inside the IVI chamber is one of the important limitations of the study.

## Conclusion

The recent widespread use of IVI ophthalmology treatments and the increasing number of patients requiring treatment limit the use of the existing sterile operating room environment. Considering the cost, labor force, and patient compliance with the treatment, it seems more profitable to administer IVI to patients on an outpatient basis using an injection booth in a clean room. Patients' access to treatment was facilitated, and time was saved. In our clinic, IVI has been safely administered with a 0% endophthalmitis rate by creating an environment suitable for operating room sterility with the IVI cabinet system in a semi-sterile room for 1 year.

**Ethics Committee Approval:** This study was approved by Giresun Education and Research Hospital Ethics Committee (date: 28.03.2024, number: 28.03.2024-03).

**Peer-review:** Externally peer-reviewed.

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