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Reduced Incidence of Intravitreal Injection–Related Endophthalmitis With Prefilled Syringes

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Abstract

Purpose: To evaluate the incidence and clinical characteristics of intravitreal injection–related endophthalmitis cases with antivascular endothelial growth factor (anti-VEGF) medications manufactured as prefilled syringes or non-prefilled preparations. **Methods:** This retrospective chart review comprised eyes that received intravitreal anti-VEGF at a single-specialty retina practice from January 1, 2014, to December 31, 2019. Eyes diagnosed with injection-related endophthalmitis were identified. Demographic and clinical data were abstracted from medical records, including the type of anti-VEGF agent, baseline and follow-up corrected visual acuity (VA), and microbiologic findings. **Results:** The review identified 88 cases of intravitreal anti-VEGF injection–related endophthalmitis and 325 990 total injections. Total injections included 32 045 (9.8%) bevacizumab (BEV), 93 073 (28.6%) ranibizumab (RAN), 122 947 (37.7%) aflibercept (AFL), and 77 925 (23.9%) ranibizumab prefilled syringe (RANPFS). Ten of the endophthalmitis cases were related to BEV, 21 to RAN, 45 to AFL, and 12 to RANPFS. The endophthalmitis rate was lowest for RANPFS (0.0154%) (BEV, 0.0312%; RAN, 0.0226%; AFL, 0.0366%) ($P = .030$). Thirty-four (41.5%) of 82 samples were culture positive. RANPFS had a significantly lower rate of culture-proven postinjection endophthalmitis than the other agents ($P = .003$). The mean VA for endophthalmitis cases related to RANPFS vs non-prefilled agents was similar at presentation (Snellen 20/2092 vs 20/2327) and at the 3-month follow-up (Snellen 20/201 vs 20/272) (both $P > .05$). **Conclusions:** Anti-VEGF medications in prefilled syringes may reduce the risk for medication contamination during injection preparation. RANPFS was associated with a lower rate of injection-related endophthalmitis than non-prefilled anti-VEGF medications.

Keywords

retina, choroidal neovascularization, retinal vascular disease, anti-VEGF agents, endophthalmitis, inflammatory and infectious diseases, wet AMD (neovascular), dry AMD (non-neovascular), retinal neovascularization

Introduction

Endophthalmitis is a sight-threatening inflammatory reaction in the vitreous body that can result in significant damage to ocular tissues.[1] In some cases, vitreous inflammation occurs as part of a sterile immune reaction; however, more often it manifests in response to the presence of intraocular pathogens.[2–6] Infectious organisms can be introduced into the eye after operative and office-based procedures such as cataract surgery and intravitreal injections.[7–15]

Over the past 2 decades, intravitreal drug delivery has become a common treatment modality for a number of retinovascular, degenerative, and inflammatory conditions of the posterior segment.[16] In particular, antivascular endothelial growth factor (anti-VEGF) medications have become widely used to manage common retinal conditions such as neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and retinal vein occlusion (RVO).[17] As a result, reports of complications such as postinjection endophthalmitis have also increased.[2,4,8,9,11,14,15,18,19]

Previous studies have described both sterile and culture-proven endophthalmitis after intraocular administration of various anti-VEGF medications.[5,6,15] While rare, these complications can result in severe vision loss, particularly if not identified and treated in a timely fashion.[20] As a result, many studies have analyzed the injection procedure to identify practice patterns that

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could potentially increase the risk for infection.[8,9,13,21] In particular, some have suggested that potential contamination might occur when medications are manually transferred from a packaged vial into a separate injection syringe.[22]

In an effort to minimize variables that could lead to drug contamination, in addition to reducing preparation time, pharmaceutical companies have manufactured anti-VEGF medications in prefilled syringes.[23–25] Although there is some evidence that prefilled syringes reduce the incidence of endophthalmitis,[22,26] existing studies mainly relied on aggregated data from multiple practices or even nationwide databases, which could have introduced significant confounding variables ranging from drug handling to injection protocols. Additional postmarketing studies from single-specialty retina practices with relatively standard injection protocols may further elucidate whether prefilled preparations have a significant impact on the rates of postinjection endophthalmitis.

This study evaluated the real-world incidence and clinical characteristics of postinjection endophthalmitis cases after the administration of anti-VEGF medications manufactured as prefilled syringes and non-prefilled preparations at a single-specialty retina practice over a 6-year period.

Methods

This retrospective chart review comprised eyes that received intravitreal anti-VEGF at a multilocation single-specialty retina practice from January 1, 2014, to December 31, 2019. Eyes diagnosed with injection-related endophthalmitis were identified.

Institutional review board approval was obtained, and the requirement for informed consent was waived. This study complied with the US Health Insurance Portability and Accountability Act of 1996 and followed the tenets of the Declaration of Helsinki.

For eyes diagnosed with injection-related endophthalmitis, demographic and clinical data, including corrected visual acuity (VA), ocular history, examination findings, type of anti-VEGF agent, and microbiologic results, were abstracted from the medical records. All eyes had an aqueous or vitreous tap and intravitreal injection of vancomycin and ceftazidime as part of initial management; a subset of these eyes required subsequent pars plana vitrectomy (PPV) for refractory endophthalmitis. Eyes with fewer than 2 months of follow-up were excluded from the visual outcome analysis.

Injection technique varied based on physician preference; however, standard infection precautions were used across all sites and protocols did not significantly change throughout the study period. All physicians performed hand washing or used an alcohol-based sanitizer; some also wore gloves. All were encouraged to follow a no-talking policy during the injection procedure. Physicians, technicians, and patients did not wear medical face masks because all procedures were performed before the COVID-19 pandemic. Local anesthesia was based on physician preference and comprised topical proparacaine eyedrops, proparacaine cotton-tip pledgets, or subconjunctival lidocaine. Povidone–iodine 5% prep was administered by the physician or by a technician under direct physician supervision, except in cases with a previously documented allergic reaction, in which case benzalkonium chloride prep was used.

Within the practice, offices were separated into 2 pods, denoted here as pod A and pod B. Infection precautions for the handling of non-prefilled anti-VEGF medications were standardized across all offices; however, in pod A the physician routinely drew up medications for intravitreal injection, while in pod B the ophthalmic technician routinely drew up medications. Ophthalmic technicians received education in infection prevention and demonstrated proficiency in medication handling as part of standard job training.

All statistical analyses were performed with XLSTAT (Addinsoft). Descriptive statistics were used to assess baseline clinical characteristics and demographic data. Chi-square testing was performed to evaluate significant differences between categorical variables. Logistic regressions were used to model associations between continuous variables and binary clinical outcomes. The level of significance was set at $P < .05$.

Results

Eighty-eight eyes of 88 patients with intravitreal injection–related endophthalmitis were identified among 325 990 anti-VEGF injections, for a cumulative rate of 0.0270%, or 1 in 3704 intravitreal injections. The anti-VEGF injections included bevacizumab (BEV), ranibizumab (RAN), aflibercept (AFL), and ranibizumab prefilled syringe (RANPFS). The mean age of patients who developed endophthalmitis was 78 years. Treatment indications for eyes with endophthalmitis included nAMD (67%), DME or proliferative diabetic retinopathy (17%), RVO (6%), and neovascular glaucoma (1%)

Table 1 shows the total number and rate of endophthalmitis cases associated with each anti-VEGF agent. RANPFS had the lowest overall rate of endophthalmitis (0.0154%; 1 in 6494 injections) of all the agents (cumulative rate 0.0306%; 1 in 3268 injections) ($P = .030$). Direct comparisons between agents showed that RANPFS had a significantly lower rate of endophthalmitis than AFL ($P = .006$); however, the difference in endophthalmitis rates was not significant for all other comparisons (all $P > .05$), including RANPFS vs RAN ($P = .288$).

Endophthalmitis rates for each medication were also analyzed by year from 2014 through 2019; RANPFS was introduced in 2017. In 2014, AFL (0.0817%) was associated with a higher rate of endophthalmitis than BEV (0%) and RAN (0.0156%) ($P = .038$ and $P = .002$, respectively). In 2017, AFL was associated with a higher rate of endophthalmitis (0.0564%) than RANPFS (0.0107%) ($P = .014$). Endophthalmitis rates were not significantly different between any other medications within each year from 2014 through 2019. As such, there was no significant difference in the endophthalmitis rate between RAN and RANPFS cumulatively or within any year from 2017 through 2019.

Table 1. Total Number of Endophthalmitis Cases for Each Intravitreal Anti-VEGF Agent.

Agent	Endophthalmitis Cases (n)	Total Injections, n (%)	Endophthalmitis Rate (%)
BEV	10	32 045 (9.8)	0.0312
RAN	21	93 073 (28.6)	0.0226
AFL	45	122 947 (37.7)	0.0366
RANPFS	12	77 925 (23.9)	0.0154
Total	88	325 990 (100.0)	0.0270

Abbreviations: AFL, aflibercept; BEV, bevacizumab; RAN, ranibizumab; RANPFS, ranibizumab prefilled syringe; VEGF, vascular endothelial growth factor.

Analysis comparing practice locations showed a significantly higher rate of intravitreal injection–related endophthalmitis in pod B (62 cases in 140 476 injections; rate 0.0334%), where technicians routinely drew up injection medications, than the rate in pod A (26 cases in 185 514 injections; rate 0.0185%) ($P = .010$), where physicians routinely drew up injection medications; this finding remained significant when excluding RANPFS injections ($P = .013$). Pod comparisons for each agent individually showed a significantly higher rate of endophthalmitis for AFL ($P = .035$) in pod B than in pod A but no significant difference for BEV ($P = .934$), RAN ($P = .063$), or RANPFS ($P = .321$).

Regarding the aqueous or vitreous tap, 82 samples underwent microbiologic processing and 34 (41.5%) returned culture positive. Culture results were not available for 6 cases, presumably as a result of inadequate samples or complications related to the handling or processing of samples by the microbiology laboratory. Culture results included coagulase-negative staphylococci (19), *Staphylococcus aureus* (4), methicillin-resistant *Staphylococcus aureus* (1), viridans streptococci (4), *Enterococcus faecalis* (4), *Pseudomonas aeruginosa* (1), and other gram-negative rod species (1). Among the 34 culture-proven cases, 3 (0.0094%) were associated with BEV, 6 (0.0064%) with RAN, 23 (0.0187%) with AFL, and 2 (0.0026%) with RANPFS. The 2 cases related to RANPFS grew *Pseudomonas aeruginosa* and coagulase-negative staphylococci. Overall, RANPFS had a significantly lower rate of culture-proven postinjection endophthalmitis than the other agents ($P = .003$). AFL had a higher rate of culture-proven endophthalmitis than RAN ($P = .015$) and RANPFS ($P = .002$), but there was no significant difference compared with BEV ($P = .250$). Rates of culture-proven endophthalmitis did not significantly differ between RANPFS and BEV ($P = .092$), RANPFS and RAN ($P = .243$), or RAN and BEV ($P = .596$).

The mean VA was 20/2410 (logMAR 2.081) at presentation with endophthalmitis and 20/258 (logMAR 1.110) at the 3-month follow-up. Five eyes with fewer than 3 months of follow-up were excluded from the visual outcome analysis. In the 23 eyes that had PPV after initial management, the mean VA was 20/4418 (logMAR 2.344) at presentation and 20/1283 (logMAR 1.807) at the 3-month follow-up. PPV was performed in 40% (4/10) of endophthalmitis cases that received BEV, 24% (5/21) that received RAN, 27% (12/45) that received AFL, and 17% (2/12) that received RANPFS. There was no significant difference in the rate of PPV for endophthalmitis based on the type of anti-VEGF agent received ($P = .655$). There was also no significant difference in the mean VA between endophthalmitis cases related to RANPFS and cases related to non-prefilled agents at presentation (Snellen 20/2092 vs 20/2327; logMAR 2.019 vs 2.066) or at the 3-month follow-up (Snellen 20/201 vs 20/272; logMAR 1.002 vs 1.133) (both $P > .05$).

Conclusions

The present study furthers our understanding of the real-world incidence and clinical characteristics of postinjection endophthalmitis associated with the use of anti-VEGF medications manufactured in prefilled syringes and non-prefilled preparations. Compared with aggregate reports from multiple practices or nationwide registries,[22,26] the results of this single practice–based study may represent findings in the context of fewer confounding protocol variations, albeit as a consequence it may also be less generalizable to other practices.

Consistent with previous reports, this study found that the rates of postinjection culture-proven endophthalmitis were lower with RANPFS than with other non-prefilled anti-VEGF preparations.[22] However, in our cohort RANPFS had a statistically significantly lower rate of culture-proven endophthalmitis than AFL; however, the difference compared with RAN or BEV did not reach statistical significance. This may, in part, be because AFL was the most commonly used non-prefilled agent during the study period. Also, postinjection endophthalmitis is a relatively rare phenomenon; thus, it is possible that analyses comparing RANPFS with RAN or BEV were relatively underpowered.

The preparation and administration of intravitreal injections are often performed meticulously and systematically in an effort to reduce the risk for infection, yet protocols and preferences may vary among physicians and institutions. For instance, some practices commonly use topical antibiotics before and after intravitreal injections despite limited evidence of a decreased infection risk, and others routinely use a gel-based topical anesthetic even though studies suggest a slightly increased risk for endophthalmitis.[9,13,18,21]

The transfer of medication from vial to syringe could be another instance during which contaminants are introduced. In our cohort, endophthalmitis rates were 1.81 times higher in offices where the technician typically drew up injection medications (0.0334%) than in offices where the physician typically drew up medications (0.0185%), even though both groups used

standard protocols for infection prevention and medication handling. This disparity might instead reflect the more comprehensive and nuanced training in sterile technique that physicians usually acquire throughout their medical and surgical education. Notably, there was no difference in the rate of endophthalmitis between offices when analyzing RANPFS only, indicating that prefilled syringes effectively reduce the risk for medication contamination during injection preparation.

From a microbiologic standpoint, oral-associated flora was identified in 8 (24%) of 34 culture-proven cases (4 viridans streptococci, 4 *Enterococcus faecalis*) with conventional anti-VEGF preparations compared with none with RANPFS. Storey et al[22] similarly reported growth of oral-associated flora in 27.3% of endophthalmitis cases associated with conventionally prepared RAN and none in the prefilled RAN group. These data suggest that prefilled syringes might reduce the likelihood of contamination with oral pathogens during injection preparation and administration. However, these conclusions may have limited generalizability after the COVID-19 pandemic because patients and medical personnel are routinely required to wear face masks in healthcare settings.[27,28] The Writing Committee for the Post-Injection Endophthalmitis Study Group et al[29] reported decreased rates of culture-positive postinjection endophthalmitis with universal mask wearing but no significant difference in the overall risk for presumed acute bacterial endophthalmitis. Nonetheless, it is important to recognize that patients wearing ill-fitting face coverings and surgical masks without a proper seal or adhesive over the nose and cheek could potentially experience increased ocular exposure to oral pathogens as a result of upward airflow during exhalation.[30,31]

The VA was slightly better in endophthalmitis cases associated with RANPFS than in those associated with non-prefilled preparations at presentation and at the 3-month follow-up; however, this relationship was not statistically significant. Similar to previous studies, PPV was performed in eyes with a mean VA between counting fingers and hand motions at 1 ft.[15] Storey et al[22] reported that endophthalmitis cases related to prefilled ranibizumab may lose fewer lines of vision than those related to conventionally prepared ranibizumab at the 6-month follow-up. However, these results might not be directly comparable because our study also included eyes that received AFL and BEV. In addition, our study had a shorter follow-up, a greater proportion of patients who had PPV, and different proportions of eyes with particular treatment indications. As prefilled preparations of BEV, RAN, AFL, and other new anti-VEGF agents become more widespread, additional studies may further elucidate the rates of endophthalmitis and visual outcomes associated with prefilled versus conventionally prepared medications.

Postinjection endophthalmitis remains a relatively rare occurrence; therefore, certain limitations of existing studies may stem from the aggregation of data from multiple practices or nationwide registries. Although this single practice–based study involved fewer confounding protocol variations, it was more limited in terms of study size and generalizability. This study was also limited by its retrospective nature. Nonetheless, combined efforts from manufacturers and healthcare personnel are necessary to further reduce the risk for intraocular infection.

In conclusion, our results indicate that ranibizumab manufactured in a prefilled syringe is associated with reduced rates of injection-related endophthalmitis, possibly as a result of the reduced risk for contamination during injection preparation. As new intravitreal agents are developed, manufacturers should consider prefilled syringes as one method to potentially reduce the risk for injection-related endophthalmitis.

Authors' Note

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Ethical Approval

The requirement for informed consent was waived due to the retrospective nature of the study. Participation in the study involved no more than minimal risk to study subjects, and waiver of informed consent did not adversely impact the welfare or rights of study subjects.

Statement of Informed Consent

Institutional review board approval was obtained from New England IRB (ID 1538140). This study complied with the US Health Insurance Portability and Accountability Act of 1996 and followed the tenets of the Declaration of Helsinki.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr. Roth is a consultant to Alimera Sciences, and has received royalties from Genentech.

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