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Viewpoint:
Use of topical antibiotics with intravitreal injections

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Objectives

To review the current use of topical antibiotics with intravitreal injections

To highlight areas where current evidence could better inform clinical practice

To present the recommendations of the Vision Academy on this topic

The Vision Academy provides ophthalmic specialists with a forum to share existing skills and knowledge, build best practice, and lead the wider community in the drive towards optimized, compassionate patient care.

Through their collective expertise, the Vision Academy seeks to provide guidance for best clinical practice in the management of retinal disease, particularly in areas with insufficient conclusive evidence.

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What are the challenges surrounding the use of topical antibiotics?

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Background

Current use of topical antibiotics with intravitreal injections is based on historical protocols

Intravitreal injections are increasing in frequency due to the widespread adoption of anti-VEGF therapies for the management of retinal diseases.

However, serious complications of intravitreal injections include infectious endophthalmitis

The use of topical antibiotics with intravitreal injections to prevent infection is largely historical, based on surgical practice and protocols from the initial clinical trials of anti-VEGF

As a result, initial product information / drug labels included a recommendation for topical antibiotic use, leading to routine use by many, despite evidence to suggest that this does not represent best practice

Further, the low incidence of infectious endophthalmitis means that RCTs are not feasible, so we must rely on data from phase III / IV studies and large retrospective series

CLINICAL CHALLENGE

Evidence-based guidelines on the use, or otherwise, of topical antibiotics during intravitreal injection procedures are lacking

RCT, randomized controlled trial; VEGF, vascular endothelial growth factor.

Merani R, Hunyor AP. *Int J Retina Vitreous* 2015; 1: 9.

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What is the significance of endophthalmitis?

- Endophthalmitis is an uncommon, potentially devastating complication of intravitreal injection[1]
  - Occurrence of endophthalmitis ranges from 1 in 1000 to 1 in 5000 injections[2]
  - Commonly caused by coagulase-negative *Staphylococcus* and *Streptococcus*[1-3]
  - Despite appropriate and prompt therapy, visual outcomes are often poor[3]
- Risk reduction strategies for the prevention of endophthalmitis are particularly important for improving overall patient outcomes[3]

1. Sachdeva MM *et al. J Ophthalmic Inflamm Infect* 2016; 6 (1): 2; 2. Sigford DK *et al. Clin Ophthalmol* 2015; 9: 773–781;
3. Schwartz SG *et al. Curr Pharm Des* 2015; 21 (32): 4703–4706.

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Worldwide experience highlights low incidence of endophthalmitis

Country	Article title	Citation	Overall incidence of post-injection endophthalmitis, %
	Endophthalmitis After Intravitreal Injections: Incidence, Presentation, Management, and Visual Outcome	Dossarps D *et al.* *Am J Ophthalmol* 2015; 160 (1): 17–25	0.021
	Endophthalmitis After Anti-VEGF Injections	Klein KS *et al.* *Ophthalmology* 2009; 116 (6): 1225.e1	0.049
	Incidence and Clinical Features of Post-injection Endophthalmitis According to Diagnosis	Rayess N *et al*. *Br J Ophthalmol* 2016; 100 (8): 1058–1061	0.038
 	Low Endophthalmitis Rates After Intravitreal Anti-vascular Endothelial Growth Factor Injections in an Operation Room: A Retrospective Multicenter Study	Freiberg FJ *et al.* *Retina* 2017; 37 (12): 2341–2346	0.0074
	Post-intravitreal anti-VEGF endophthalmitis in the United Kingdom: incidence, features, risk factors, and outcomes	Lyall D *et al*. *Eye* 2012; 26: 1517–1526	0.025

VEGF, vascular endothelial growth factor.

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Approaches to prevent endophthalmitis

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Endophthalmitis prevention strategies

Meticulous preparation

- Avoidance of needle contact with eyelashes
- Eyelid speculum
- Drapes

Careful attention paid to aseptic technique

- Use of sterile gloves

Povidone-iodine use

- On ocular surface, in conjunctival cul-de-sac

Reduce aerosolized droplets containing oral contaminants

Prevent movement of conjunctiva over injection site

Use of topical antibiotics

Postpone injections in patients with active external infections

Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis (e.g., eye pain, redness of the eye, photophobia, and blurring of vision) without delay

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Evidence on the use of topical antibiotics with intravitreal injections

What is the rationale for the use of topical antibiotic prophylaxis for intraocular procedures?

For incisional surgery where there is an external surgical wound that may not always be completely sealed (e.g., sutureless phaco), there is a sound theoretical rationale for topical antibiotic prophylaxis

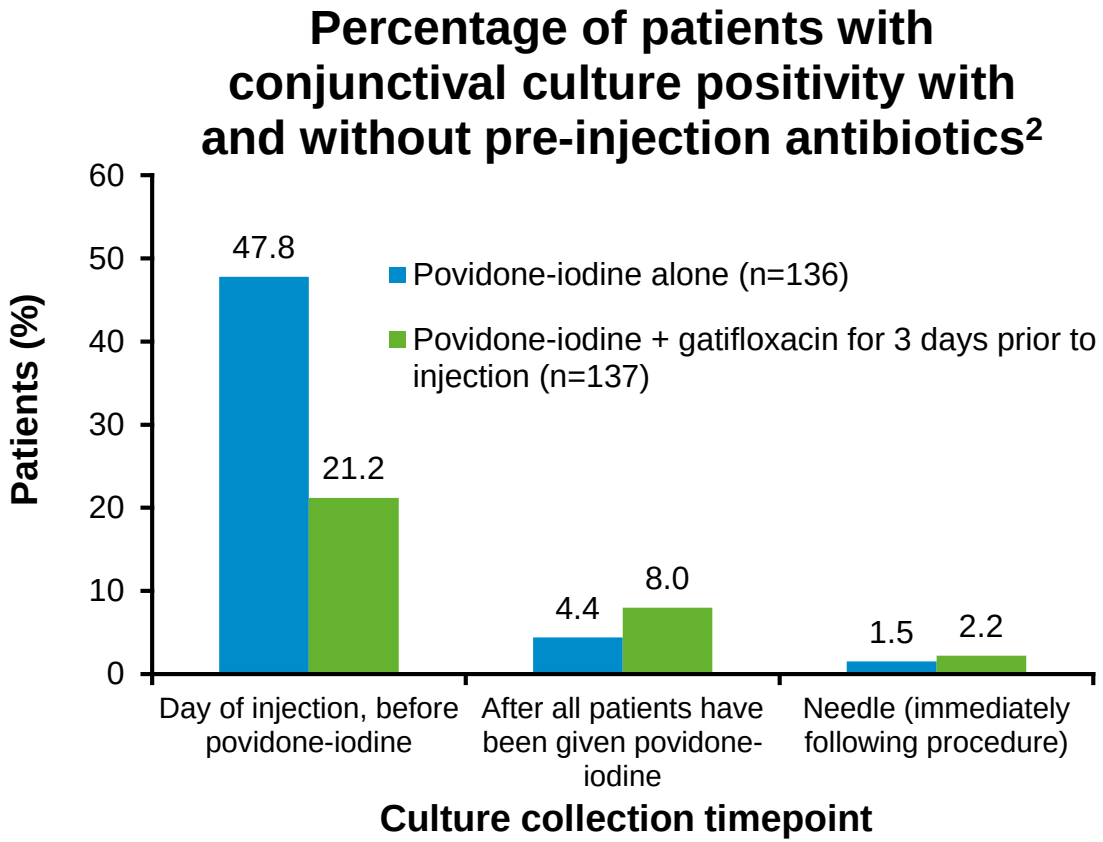
However, such a wound is seldom present when intravitreal injections are given, especially when using a 30-gauge needle (at the largest, 27-gauge)

A major factor that sets intravitreal injections apart from other invasive procedures is the **repeated nature of the injections in many cases**

Hunyor AP *et al. Acta Ophthalmol* 2017 Apr 25. doi: 10.1111/aos.13417. [Epub ahead of print]

Pre-injection antibiotics are not associated with lower bacterial loads at the injection site*

- The use of topical antibiotics (combined with povidone-iodine) before cataract surgery has been shown to result in reduced colony counts[1]
- This benefit does not appear to translate to the use of topical antibiotics administered before an intravitreal injection
- **There is no additional benefit of pre-injection antibiotic use** when combined with povidone-iodine
  - Povidone-iodine reduces the number of bacterial colonies by 91%[3]
  - Povidone-iodine lowers the risk of endophthalmitis to 0.06% (vs. 0.24% with silver protein solution)[4]



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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

Should topical antibiotics be used with intravitreal injections?

RECOMMENDATION

*When given in addition to povidone-iodine.

1. Isenberg SJ *et al. Arch Ophthalmol* 1985; 103 (9): 1340–1342; 2. Moss JM *et al. Ophthalmology* 2009; 116 (8): 1498–1501;
3. Apt L *et al. Arch Ophthalmol* 1984; 102 (5): 728–729; 4. Speaker MG, Menikoff JA. *Ophthalmology* 1991; 98 (12): 1769–1775.

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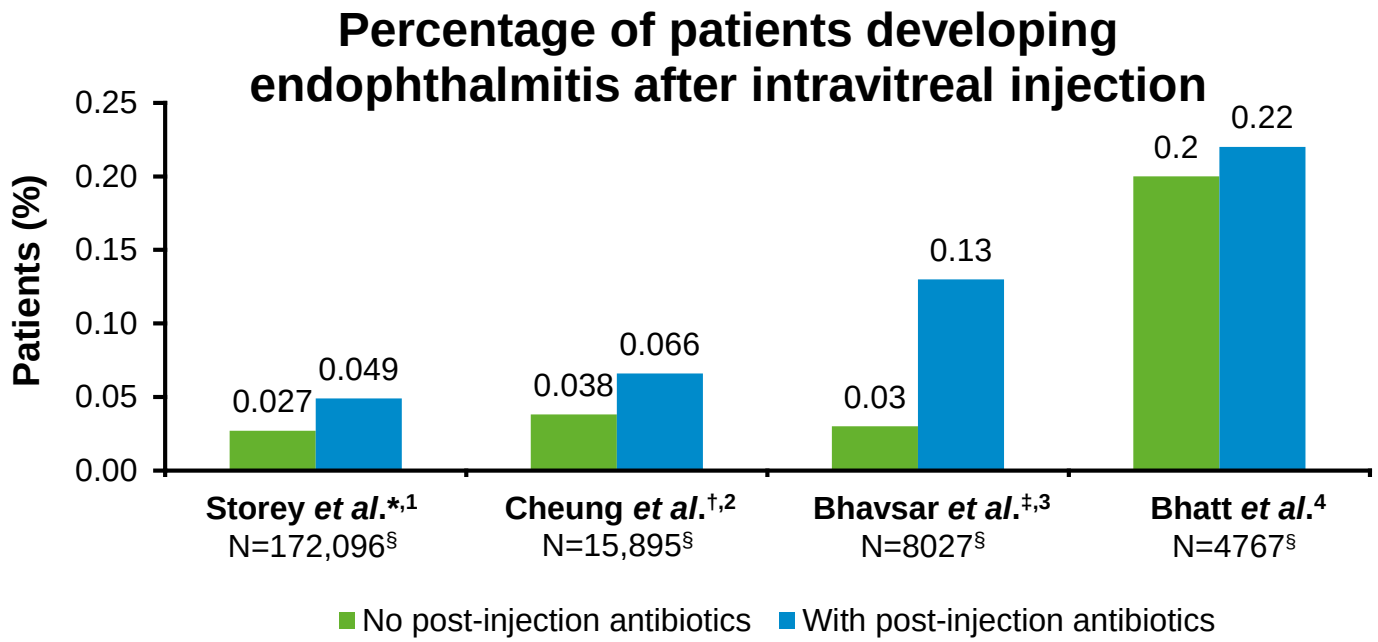
Post-injection antibiotics have no effect on the rate of endophthalmitis

- Large studies have shown that the use of post-injection antibiotics does not reduce the incidence of endophthalmitis[1-4]



- A similar outcome was also reported in one of the largest (316,576 injections), retrospective, nationwide studies conducted in France[5]

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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

Should topical antibiotics be used following intravitreal injections?

RECOMMENDATION

*For the Post-Injection Endophthalmitis Study Team. †8259 patients were given antibiotics for 5 days after injection; 2370 patients received antibiotics immediately after injection. ‡For the Diabetic Retinopathy Clinical Research Network. §Injections.

1. Storey P *et al. Graefes Arch Clin Exp Ophthalmol* 2016; 254 (2): 235–242; 2. Cheung CS *et al. Ophthalmology* 2012; 119 (8): 1609–1614;
3. Bhavsar AR *et al. Arch Ophthalmol* 2012; 130 (6): 809–810; 4. Bhatt SS *et al. Retina* 2011; 31 (10): 2032–2036;
5. Dossarps D *et al. Am J Ophthalmol* 2015; 160 (1): 17–25.e1.

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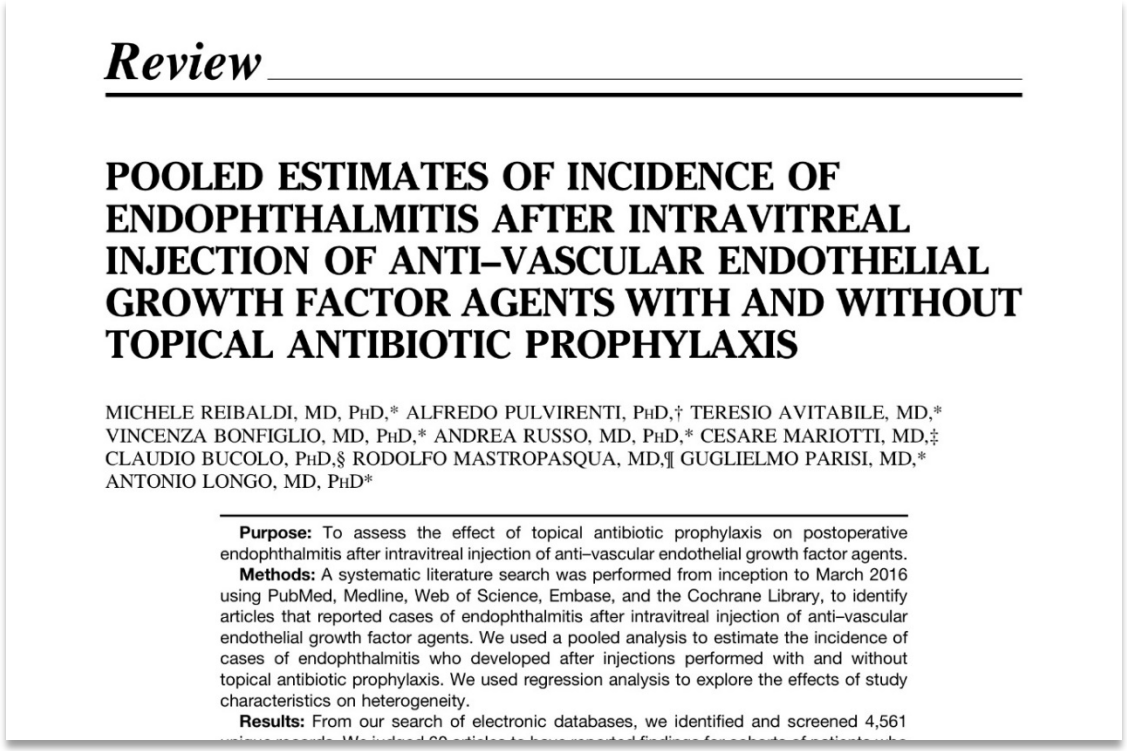
Higher incidence of endophthalmitis WITH antibiotics



Review

POOLED ESTIMATES OF INCIDENCE OF ENDOPHTHALMITIS AFTER INTRAVITREAL INJECTION OF ANTI–VASCULAR ENDOTHELIAL GROWTH FACTOR AGENTS WITH AND WITHOUT TOPICAL ANTIBIOTIC PROPHYLAXIS

MICHELE REIBALDI, MD, PHD,* ALFREDO PULVIRENTI, PHD,† TERESIO AVITABILE, MD,* VINCENZA BONFIGLIO, MD, PHD,* ANDREA RUSSO, MD, PHD,* CESARE MARIOTTI, MD,‡ CLAUDIO BUCOLO, PHD,§ RODOLFO MASTROPASQUA, MD,¶ GUGLIELMO PARISI, MD,* ANTONIO LONGO, MD, PHD*

Purpose: To assess the effect of topical antibiotic prophylaxis on postoperative endophthalmitis after intravitreal injection of anti–vascular endothelial growth factor agents.
Methods: A systematic literature search was performed from inception to March 2016 using PubMed, Medline, Web of Science, Embase, and the Cochrane Library, to identify articles that reported cases of endophthalmitis after intravitreal injection of anti–vascular endothelial growth factor agents. We used a pooled analysis to estimate the incidence of cases of endophthalmitis who developed after injections performed with and without topical antibiotic prophylaxis. We used regression analysis to explore the effects of study characteristics on heterogeneity.
Results: From our search of electronic databases, we identified and screened 4,561

- This paper identified and screened 4561 records:
  - 60 articles met the inclusion criteria (12 arms of RCTs, 11 prospective cohorts, and 37 retrospective cohorts)
  - 244 cases of endophthalmitis
  - 639,391 intravitreal injections of anti-VEGF

The final pooled estimate of endophthalmitis proportions was higher in the antibiotic-treated group:

0.09% (95% CI, 0.07–0.12) in the **antibiotic-treated** group	0.03% (95% CI, 0.02–0.05) in the **untreated** group

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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

Should topical antibiotics be used with intravitreal injections?

RECOMMENDATION

CI, confidence interval; RCT, randomized controlled trial; VEGF, vascular endothelial growth factor.
Reibaldi M *et al. Retina* 2018; 38 (1): 1–11.

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The majority of studies do not show a difference in endophthalmitis rates with antibiotic use

Study	Injections	Retinal diseases treated	Endophthalmitis rate with topical antibiotics	Endophthalmitis rate without topical antibiotics	Statistical significance
Bhatt *et al.* 2011	4767	Multiple	0.22%	0.20%	Not significant
Bhavsar *et al.* 2012	8027	DME and PDR	0.13%	0.03%	Not significant
Bhavsar *et al.* 2015	18,839	Multiple	0.005%	Not applicable	Not applicable
Cheung *et al.* 2012	15,895	Multiple	0.061–0.084%	0.038%	Not significant
Falavarjani *et al.* 2013	5901	Multiple	0.10%	0%	Not significant
Falavarjani *et al.* 2015	8037	Multiple	0.01%	0%	Not significant
Meredith *et al.* 2015	18,509	Neovascular AMD	0.04–0.08%	0.15%	Not significant
Park *et al.* 2013	17,332	Multiple	0%	0.035%	Not significant
Porteous *et al.* 2014	6957	Not specified	Not applicable	0.04%	Not applicable
Ramel *et al.* 2014	11,450	Not specified	0.03%	0.23%	p=0.024
Storey *et al.* 2014	117,171	Multiple	0.049%	0.032%	Not significant

?

CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

Should topical antibiotics be used with intravitreal injections?

RECOMMENDATION

AMD, age-related macular degeneration; DME, diabetic macular edema; PDR, proliferative diabetic retinopathy.

Schwartz SG *et al. Curr Pharm Des* 2015; 21 (32): 4703–4706; Reibaldi M *et al. Retina* 2018; 38 (1): 1–11.

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Many large series have reported that topical antibiotics do not decrease, and may in fact increase, the rate of endophthalmitis

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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

Should topical antibiotics be used with intravitreal injections?

RECOMMENDATION

AMD, age-related macular degeneration; DME, diabetic macular edema; PDR, proliferative diabetic retinopathy.

Schwartz SG *et al. Curr Pharm Des* 2015; 21 (32): 4703–4706; Reibaldi M *et al. Retina* 2018; 38 (1): 1–11.

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Antibiotics do not penetrate the vitreous humor

- A prospective randomized study demonstrated that topical antibiotic administration leads to effective levels in the aqueous but not in the vitreous humor
  - Concentrations in the vitreous humor did not exceed the MIC_{90} for the most common bacterial pathogens causing acute postoperative endophthalmitis

	Mean concentration in vitreous humor ± SD (µg / mL)		MIC_{90} (µg / mL)		
Topical antibiotic	**3-day pre-surgery regimen* (n=3)**	**1-hour pre-surgery regimen† (n=3)**	***Staphylococcus aureus***	***Staphylococcus epidermidis***	***Streptococcus pneumoniae***
Moxifloxacin 0.5%	0.011 ± 0.008	0.012 ± 0.011	0.064	0.047	0.125
Gatifloxacin 0.3%	0.008 ± 0.006	0.001 ± 0.0003	0.11	0.09	0.22

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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

Should topical antibiotics be used with intravitreal injections?

RECOMMENDATION

*Four doses per day for 3 days prior to surgery (patient-administered; 100% patient compliance); †One drop every 15 minutes for a total of three doses administered 1 hour prior to surgery.
MIC_{90}, minimum inhibitory concentration for 90% of isolates; SD, standard deviation.
Costello P *et al. Retina* 2006; 26 (2): 191–195.

VISION ACADEMY

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Gatifloxacin 0.3%	0.008 ± 0.006	0.001 ± 0.0003	0.11	0.09	0.22

Little rationale for topical antibiotics protecting against bacteria introduced at the time of injection

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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

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Costello P *et al. Retina* 2006; 26 (2): 191–195.

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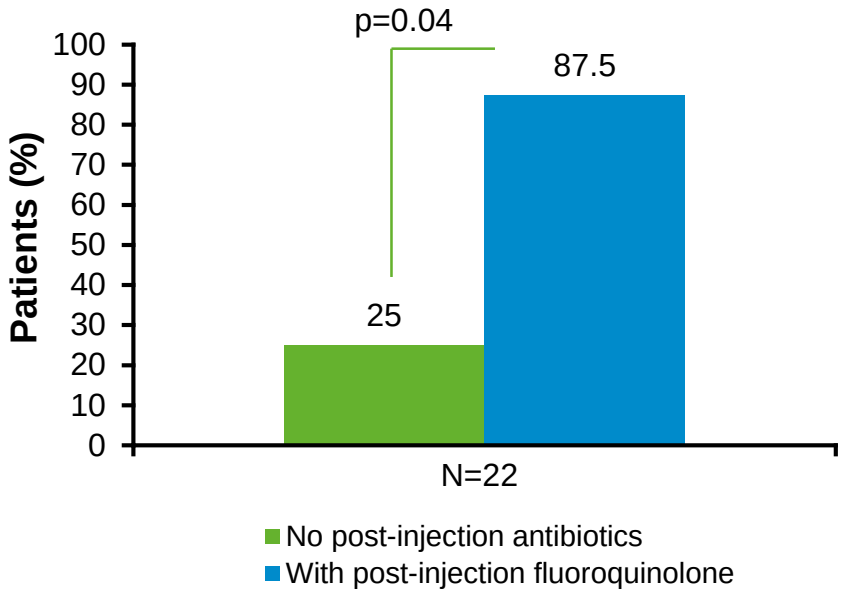
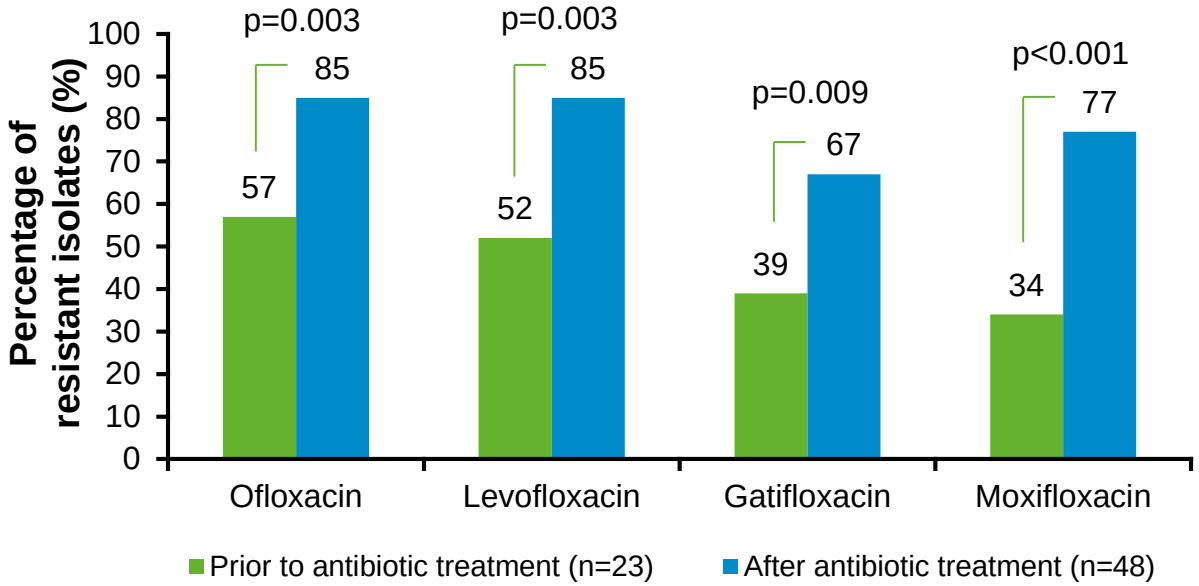
Use of topical antibiotics increases antibiotic resistance

Percentage of patients with ocular colonies resistant to fluoroquinolones[1]



Percentage of conjunctival bacterial isolates resistant to fluoroquinolones, before and after three intraocular injections with post-injection antibiotics[2]



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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

What is the impact of the use of topical antibiotics on antibiotic resistance?

RECOMMENDATION

1. Milder E *et al. Ophthalmology* 2012; 119 (7): 1420–1424; 2. Kim SJ, Toma HS. *Ophthalmology* 2011; 118 (7): 1358–1363;
3. Hsu J *et al. Am J Ophthalmol* 2014; 157 (3): 514–518.e1.

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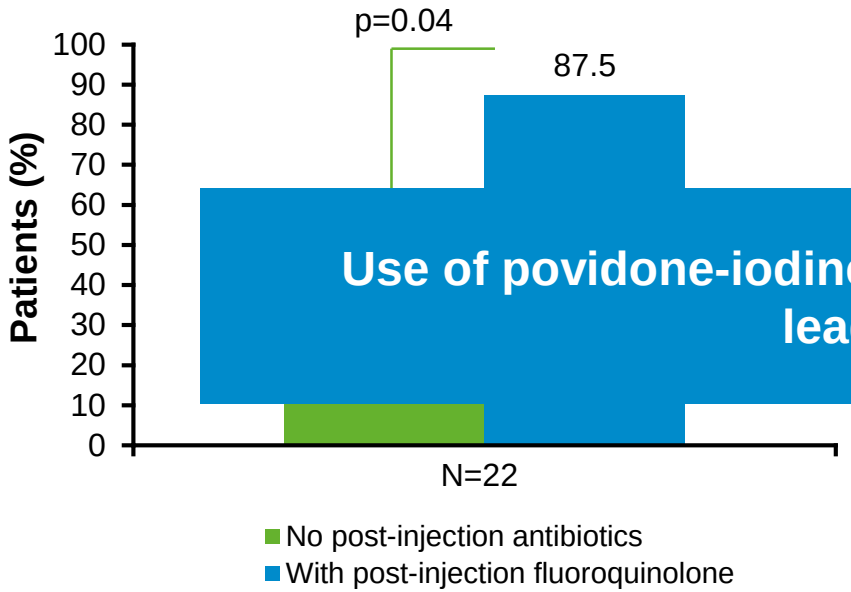
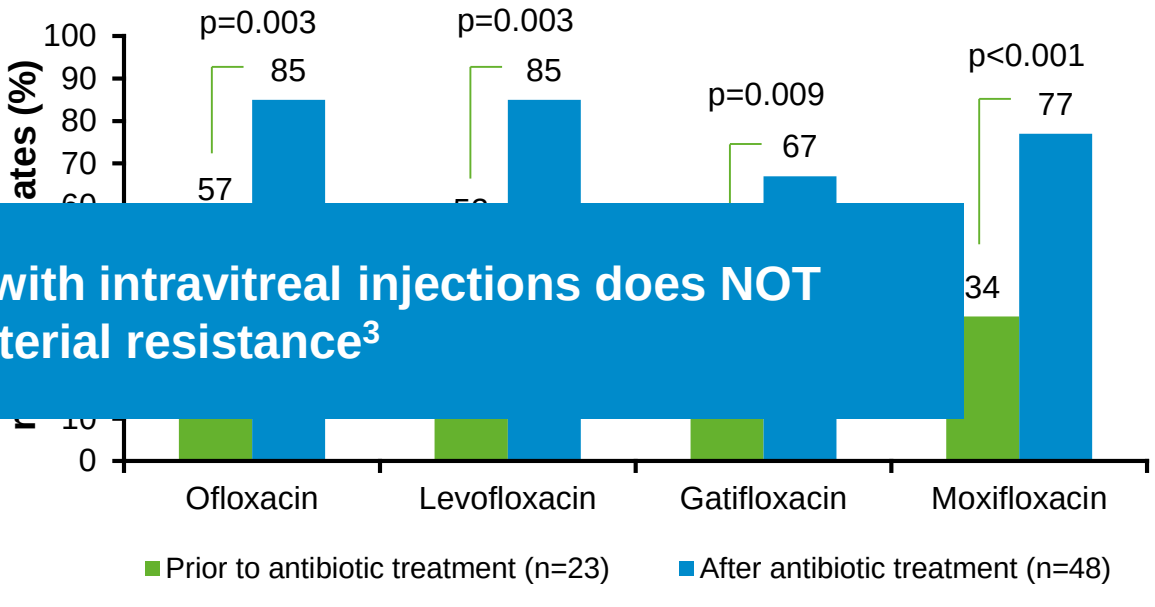
Use of topical antibiotics increases antibiotic resistance

Percentage of patients with ocular colonies resistant to fluoroquinolones[1]



Percentage of conjunctival bacterial isolates resistant to fluoroquinolones, before and after three intraocular injections with post-injection antibiotics[2]



Use of povidone-iodine alone with intravitreal injections does NOT lead to bacterial resistance[3]

CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

What is the impact of the use of topical antibiotics on antibiotic resistance?

RECOMMENDATION

1. Milder E *et al. Ophthalmology* 2012; 119 (7): 1420–1424; 2. Kim SJ, Toma HS. *Ophthalmology* 2011; 118 (7): 1358–1363;
3. Hsu J *et al. Am J Ophthalmol* 2014; 157 (3): 514–518.e1.

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Antibiotic-resistant strains may become more virulent

Rabbit models have demonstrated that antibiotic-resistant strains of *Staphylococcus epidermidis* tend to cause **earlier** and more **severe** inflammation compared with antibiotic-susceptible strains

It has been hypothesized that resistant strains are more capable of surviving in the intraocular compartment and colonizing ocular tissues, causing tissue damage or eliciting a damaging immune response

- These features and the resistant genes may then be transferred to the next generation

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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

What is the impact of the use of topical antibiotics on antibiotic resistance?

RECOMMENDATION

Miño De Kaspar H *et al*. *Ophthalmology* 2001; 108 (3): 470–478.

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Use of antibiotics can interfere with models of care and increase costs

- For patients on a PRN regimen with monthly monitoring, a requirement for pre-injection antibiotics would mean that intravitreal injections could not take place during the monitoring visit, in cases where treatment is only decided at the time of consultation, meaning that treatment has to be deferred rather than given on the day the decision is made[1]
  - Increased burden of appointments for patients and clinics
- Post-injection antibiotics have been estimated to increase the financial burden on the US healthcare system by an additional $64 million per year[2]

Burden on the patient

Additional clinic visits may affect adherence to treatment

Burden on clinic capacity

Increased clinic visits require resources and clinician time

Burden on the healthcare system

Increased costs of delivering intravitreal therapy

PRN, *pro re nata* (as needed).

1. Hunyor AP *et al. Acta Ophthalmol* 2017 Apr 25. doi: 10.1111/aos.13417. [Epub ahead of print]; 2. Chen RW *et al. JAMA Ophthalmol* 2013; 131 (7): 840–842.

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Summary

Despite the appealing theoretical rationale for topical antibiotic prophylaxis in the prevention of endophthalmitis, there is a distinct lack of evidence in its favor and growing evidence against its use

There is a lack of evidence that the use of topical antibiotics with povidone-iodine provides any additional benefits to the patient

- Povidone-iodine has been shown to be safe and highly effective in the prevention of endophthalmitis

The use of topical antibiotics is associated with antibiotic resistance, with the potential for these resistant strains to become virulent

The use of topical antibiotics may not only increase the burden on both the clinic and the patient, but it is also associated with high costs, which may have an impact on healthcare systems

Hunyor AP *et al. Acta Ophthalmol* 2017 Apr 25. doi: 10.1111/aos.13417. [Epub ahead of print]

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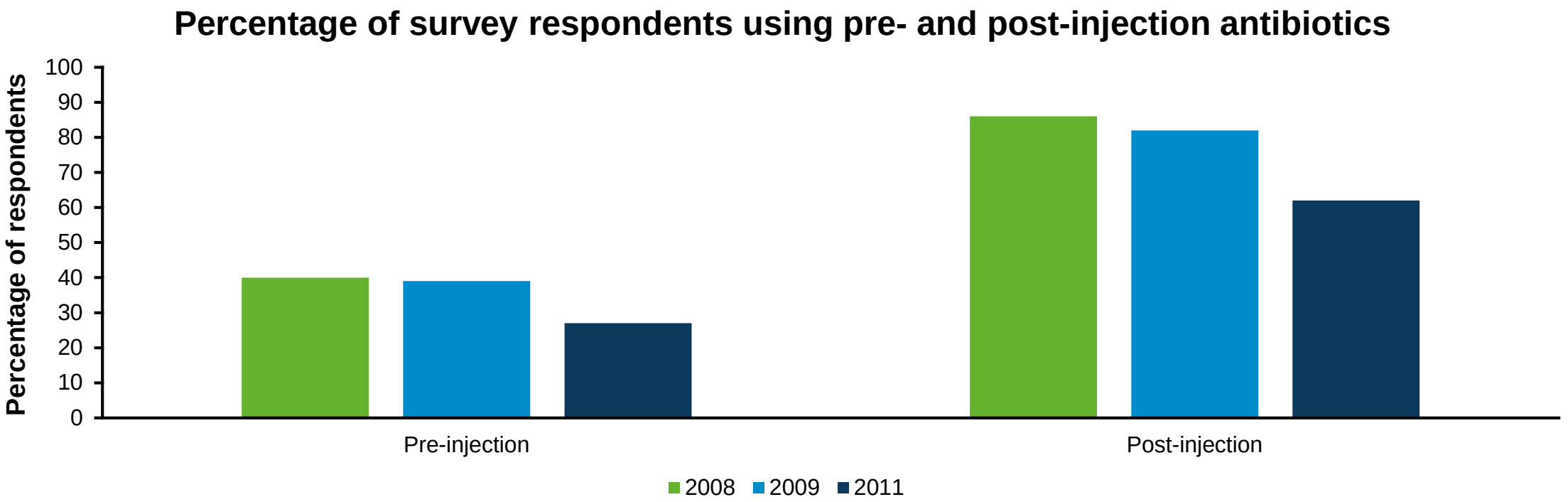
Which regions are using topical antibiotics and why?

Results from ASRS PAT surveys indicate a reduction in the use of antibiotics in the US



ASRS PAT, American Society of Retina Specialists Preferences and Trends.
Merani R, Hunyor AP. *Int J Retina Vitreous* 2015; 1: 9.

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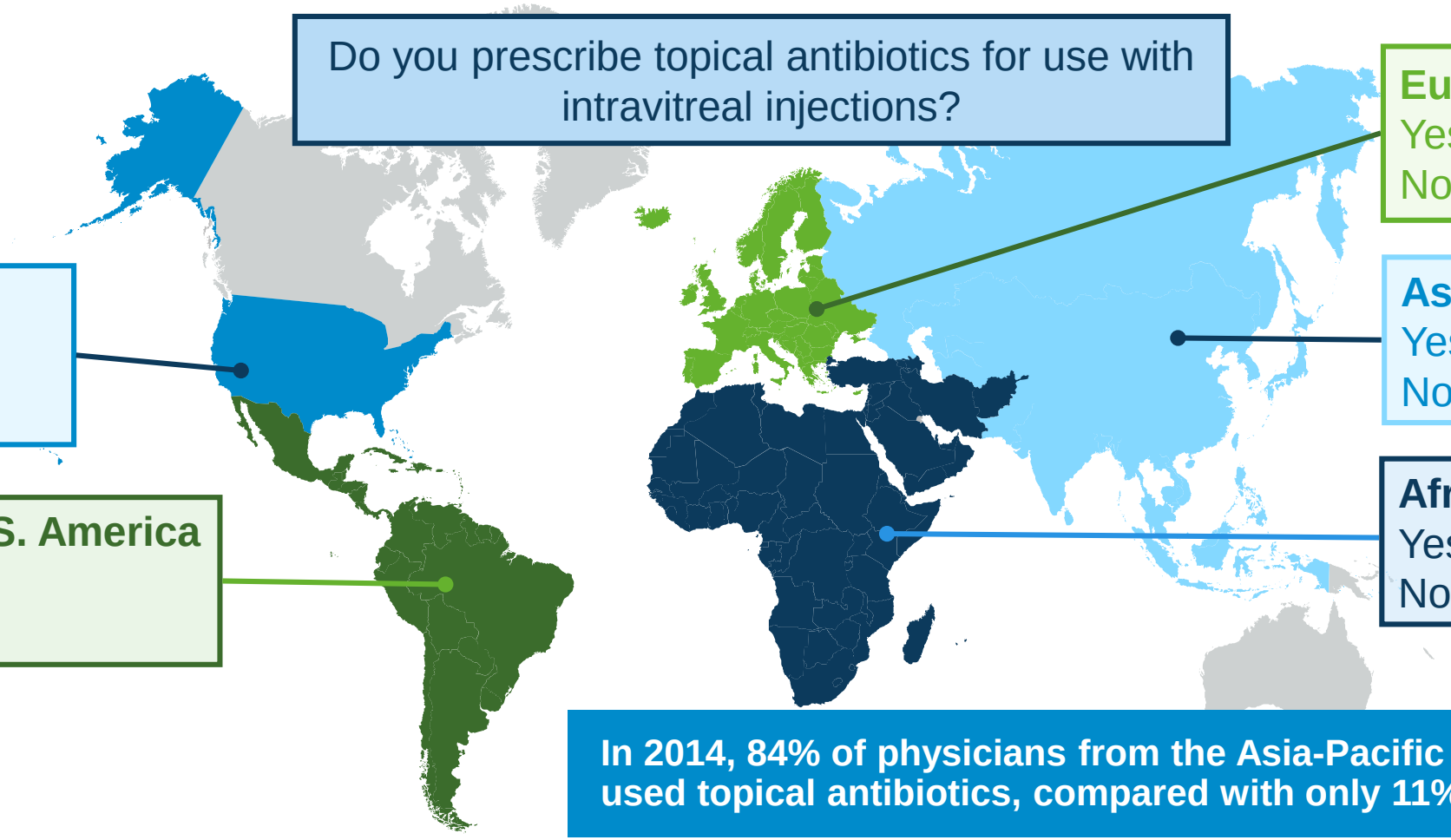
Practice habits are highly variable according to region and country

Do you prescribe topical antibiotics for use with intravitreal injections?



US
Yes 11%
No 89%

Central / S. America
Yes 86%
No 13%

Europe
Yes 81%
No 18%

Asia-Pacific
Yes 84%
No 15%

Africa / Middle East
Yes 79%
No 18%

In 2014, 84% of physicians from the Asia-Pacific region said they used topical antibiotics, compared with only 11% of US physicians

American Society of Retina Specialists. 2014. ASRS Global Trends in Retina. Available at: https://www.asrs.org/content/documents/2014_global_trends_comprehensivepostmtg.pdf. Accessed July 2016.

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Until recently, some guidelines continued to recommend the use of topical antibiotics

UK guidelines (2009 / 2018):[1]

- The Royal College of Ophthalmologists guidelines for intravitreal injection procedures in **2009** noted that the **use of post-injection topical antibiotics is recommended**
- However, when updated in **2018**, the guidelines stated that the **use of peri-injection antibiotics is no longer recommended**

US guidelines (2014):[2]

- In December **2014**, an expert US panel of 16 HCPs with expertise in various aspects of the intravitreal injection procedure convened to review and revise intravitreal injection guidelines
- An agreement was reached: **“There is insufficient evidence to support the routine use of pre-, peri, or post-injection antibiotics to reduce the rate of endophthalmitis”**

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CHALLENGE REQUIRING VISION ACADEMY GUIDANCE

What do available guidelines suggest for the use of topical antibiotics?

RECOMMENDATION

HCPs, healthcare professionals.

1. The Royal College of Ophthalmologists. 2018. Available at: https://www.rcophth.ac.uk/wp-content/uploads/2018/02/Intravitreal-Injection-Therapy.pdf. Accessed July 2018; 2. Avery RL *et al. Retina* 2014; 34 (Suppl 12): S1–S18.

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Clinical challenges

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Clinical challenges requiring guidance

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Use of topical antibiotics

- Is the use of topical antibiotics with intravitreal injections warranted?

Antibiotic resistance

- What is the impact of the use of topical antibiotics on antibiotic resistance?

Guidelines

- Do guidelines sufficiently address the use of topical antibiotics?

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Vision Academy recommendations

Use of topical antibiotics prior to, alongside, or after intravitreal injections is not recommended

Topical antibiotic use **prior to** intravitreal injection

- Most infections result from inoculation of organisms at the time of injection
- No prospective studies demonstrating that pre-injection antibiotics reduce the risk of endophthalmitis[1]

Topical antibiotic use **concurrent with** or **after** intravitreal injection

- No additional benefit of post-injection antibiotics in preventing endophthalmitis[2,3]

General consensus

Available evidence does not support a reduction in the risk of endophthalmitis with use of topical antibiotics

Topical antibiotics should not be used alongside intravitreal injections

1. Merani R, Hunyor AP. *Int J Retina Vitreous* 2015; 1: 9; 2. Li AL *et al. Retina* 2016; 36 (7): 1349–1356; 3. Storey P *et al. Ophthalmology* 2014; 121 (1): 283–289.

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There is a growing body of evidence detailing increased antibiotic resistance in patients receiving topical antibiotics

Antibiotic resistance

- Several studies have demonstrated increasing resistance of conjunctival flora to topical antibiotics[1,2]
- Resistance to fluoroquinolones, the most commonly used topical antibiotics in many regions, may have serious ramifications in other procedures (e.g., cataract surgery)

Antibiotic penetration

- Topical administration leads to effective antibiotic levels in the aqueous but not in the vitreous humor[3]

General consensus

Evidence suggests an increase in antibiotic resistance with use of topical antibiotics

Topical antibiotics should not be used alongside intravitreal injections

1. Merani R, Hunyor AP. *Int J Retina Vitreous* 2015; 1: 9; 2. Milder E *et al. Ophthalmology* 2012; 119 (7): 1420–1424;
3. Costello P *et al. Retina* 2006; 26 (2): 191–195.

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Product information for intravitreal medications and local / professional society guidelines should be updated

Significant regional differences

- Reasons for continued use of topical antibiotics with intravitreal injections include:
  - Personal preference
  - Peer pressure
  - Medico-legal concerns

- Changes in practice habits may be achieved through the revision of drug labels and the amendment of local and professional society guidelines

General consensus

Variation in opinion

Regional differences exist in the continued use of topical antibiotics with intravitreal injections

Revision of product information and guidelines is required to enable physicians to change their practice

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Summary

The Vision Academy **does not recommend the use of topical antibiotics** alongside intravitreal injections

There is a **lack of evidence** supporting any benefit for topical antibiotic prophylaxis against post-injection endophthalmitis

There is a growing body of evidence detailing **increased antibiotic resistance** in patients receiving topical antibiotics

Product information for intravitreal medications and local / professional society guidelines should be updated to reflect this recommendation and to **remove barriers to clinicians wishing to change their practice**

- Ophthalmologists should avoid inappropriate use of topical antibiotics
- Emphasis should be placed on antisepsis and aseptic technique, which are the major proven methods of endophthalmitis prevention, rather than antibiotics

The Viewpoint ‘Use of topical antibiotics with intravitreal injections’ can be downloaded from:
https://www.visionacademy.org/resource-zone/treatment-best-practices