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Evidence for and against intravitreal corticosteroids in addition to intravitreal antibiotics for acute endophthalmitis

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Abstract

The use of adjunctive intravitreal corticosteroids in endophthalmitis is controversial. Preclinical models showed that early administration of corticosteroids may be important although they reported mixed results in terms of their effects on antibiotic pharmacokinetics, control of infection and prevention of retinal damage. Most published retrospective clinical studies showed no beneficial effects associated with their use. However, a single well-conducted retrospective study showed a deleterious effect. Randomized controlled trials also showed a lack of beneficial effects. At the present time, the best available evidences do not support the routine use of adjunctive intravitreal corticosteroids for treatment of acute endophthalmitis.

Introduction

Endophthalmitis is a serious complication of ocular surgery, penetrating trauma and occasionally hematogenous spread of organisms from a distant source. Multiple advances in the treatment of this condition have been made in the last 20 years beginning with the Endophthalmitis Vitrectomy Study (EVS). The EVS found that needle vitreous biopsy obviated the need for prompt vitrectomy in patients with clinical evidence of endophthalmitis after cataract surgery or secondary intraocular lens implantation and initial visual acuity better than light perception.¹ In addition, the EVS showed that systemic antibiotics provided no additional benefit over the standard regimen of intravitreal (IVT) vancomycin and amikacin with subconjunctival and topical antibiotics combined with subconjunctival and topical corticosteroids.¹ Reports of cases of macular infarction induced by aminoglycoside (including amikacin) led to the replacement of IVT amikacin by IVT ceftazidime which had been shown to be effective against Gram-negative organisms.^{2–4} The administration of adjunctive subconjunctival antibiotics was abandoned when subsequent studies showed no influence on the final visual outcomes.^{5–6} Finally, the practice of administering corticosteroid orally was abandoned due to concerns about systemic safety with some retina specialists replacing these with IVT corticosteroids in the treatment of acute endophthalmitis.

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Conflict of Interest: none

Twenty years since the publication of the EVS, there is still no consensus regarding the role of IVT corticosteroids such as prednisolone, dexamethasone or triamcinolone acetonide in the treatment of acute endophthalmitis. In fact, the 2004 American Society of Retina Specialists Preference and Trend Survey reported an almost 50:50 split in the use of IVT corticosteroids with or without systemic corticosteroids in addition to IVT antibiotics for post-cataract endophthalmitis (43% of respondents routinely used IVT corticosteroids).⁷ The rationale for using adjunctive IVT corticosteroids mostly centers on their ability to attenuate inflammation that could theoretically lead to improved visual outcomes. The arguments against their use involve possible interference with infection control, decreased concentrations of vitreous antibiotics and increased volumes of fluid administered which may become an issue when vitreous tap cannot be obtained. Moreover, the extremely short half-life of dexamethasone makes any sustained beneficial effect unlikely. In this paper, we review the evidences for and against the use of IVT corticosteroids in addition to IVT antibiotics as initial treatment for acute endophthalmitis.

Methods

We performed a PubMed search for preclinical studies and case series examining the effect of IVT corticosteroids as an adjunct to IVT antibiotics in acute endophthalmitis. We found 18 preclinical studies examining the effect of IVT dexamethasone in acute endophthalmitis due to *Staphylococcus epidermidis*,^{8–11} *Staphylococcus aureus*,^{12–15} *Streptococcus pneumoniae*,^{16–17} *Bacillus cereus*,^{18–21} *Pseudomonas*,^{22–23} *Enterococcus faecalis*²⁴ and *Candida albicans*.²⁵ There were two preclinical studies examining the use of IVT triamcinolone acetonide in acute *Staphylococcus epidermidis*.^{26–27} There were one retrospective²⁸ and one pilot case series²⁹ looking at adjunctive IVT triamcinolone acetonide in addition to one retrospective case series looking at adjunctive IVT prednisolone³⁰ in acute endophthalmitis. There were 10 retrospective case series and 3 prospective randomized case series investigating the use of IVT dexamethasone. Of these 13 case series, one specifically looked at fungal endophthalmitis⁴¹ while the remaining involved bacterial endophthalmitis. We also reviewed studies examining the effect of IVT dexamethasone on vitreous vancomycin concentration in acute endophthalmitis.^{17, 20, 31–32}

The effect of IVT corticosteroids on vitreous antibiotic concentrations

It remains unclear how adjunctive IVT corticosteroids alter the vitreous concentrations of antibiotics. To date, no studies have examined the effect of IVT prednisolone or IVT triamcinolone acetonide on vitreous levels of antibiotics. Published studies investigating the vitreous antibiotic concentrations in the presence of IVT dexamethasone reported mixed results. There is a consensus that IVT dexamethasone significantly increases the elimination of vitreous vancomycin, leading to reduced vancomycin concentrations in normal, uninfected rabbit eyes.^{17, 32} However, the issue becomes more complicated in eyes with endophthalmitis. Specifically, in a preclinical model of *Streptococcus pneumoniae* endophthalmitis, adjunctive IVT dexamethasone significantly increased the levels of vitreous vancomycin concentration¹⁷ while in preclinical models of *Bacillus cereus* and methicillin-resistant *Staphylococcus epidermidis* endophthalmitis, the opposite result was found.^{20, 32} Nonetheless, the vitreous concentrations of vancomycin remained well above

the minimum inhibitory concentration (MIC) for *Bacillus cereus* in this study. To complicate matters further, in a prospective randomized clinical trial of suspected post-operative bacterial endophthalmitis, there was no statistically significant difference between the mean vitreous vancomycin concentrations in the presence or absence of dexamethasone.³¹ Even though a 0.2 mg (instead of the usual 1.0 mg) dose was used, the vitreous concentration of vancomycin remained above the MIC for most organisms for well over a week.³¹

The effect of IVT corticosteroids in preclinical studies of endophthalmitis

***Staphylococcus epidermidis* endophthalmitis models: IVT dexamethasone has inconsistent results**

Results in preclinical models of *Staphylococcus epidermidis* endophthalmitis were inconsistent. Three studies found less intense intraocular inflammation on clinical and/or histopathologic examination in the adjunctive IVT dexamethasone eyes.^{8, 9, 10} In contrast, a fourth study found no clinical or histopathological benefit associated with the use of IVT dexamethasone.¹¹ Of note, the histopathologic examination in the fourth study was performed at a much earlier time than in the other studies. Perhaps this did not allow sufficient time for the beneficial effect of adjunctive corticosteroid to be fully realized.

***Staphylococcus aureus* endophthalmitis models: IVT dexamethasone may be harmful in severe cases**

Staphylococcus aureus models of endophthalmitis reported contradictory results. Two studies reported a beneficial effect of adjunctive dexamethasone in inflammatory reduction and better preservation of electroretinographic (ERG) responses.^{12–13} In contrast, a third study found no significant difference clinically or histopathologically¹⁴ and a fourth study even found a significantly harmful effect.¹⁵ It should be noted that the fourth study used aphakic rabbit eyes and a much higher concentration of micro-organisms to establish endophthalmitis.¹⁵ Results from this fourth study have raised caution in the use of IVT corticosteroids in the treatment of severe endophthalmitis.

***Bacillus cereus* endophthalmitis models: no benefit of IVT dexamethasone in sterile endophthalmitis induced by *Bacillus cereus* exotoxins**

Similarly, conflicting results were reported in models of *Bacillus cereus* endophthalmitis. Two studies found significant improvement in clinical grading of the anterior segments and histopathologic grading of the posterior segments when IVT dexamethasone was added to IVT antibiotic.^{18–19} In contrast, a third study found a possible detrimental effect associated with its use.²⁰ In this study, eyes treated with adjunctive dexamethasone 6 hours post-inoculation had the lowest ERG responses among all the antibiotic treatment groups analyzed.²⁰

In sterile endophthalmitis induced by *Bacillus cereus* crude exotoxins, one study found no beneficial effect of adjunctive IVT dexamethasone.²¹ This finding is somewhat surprising considering that ocular destruction in the setting of endophthalmitis is likely a direct effect of bacterial virulence factors in addition to host inflammatory response. In this fulminant

sterile model of endophthalmitis, there was a dose-dependent increase in the severity of inflammation clinically and histopathologically.²¹ However, IVT dexamethasone failed to attenuate the host inflammatory process to produce a measurable improvement in the dexamethasone group.²¹

***Pseudomonas aeruginosa* endophthalmitis models: timing of IVT dexamethasone may be critical**

Two preclinical studies using models of *Pseudomonas aeruginosa* endophthalmitis showed that the timing of IVT dexamethasone administration was of great importance.^{22–23} The first study showed that while the addition of IVT dexamethasone to IVT antibiotic significantly reduced intraocular inflammation compared to antibiotic alone, this beneficial effect was lost when therapy was delayed more than 5 hours following the establishment of endophthalmitis.²² In fact, when treatment was initiated 10 hours after the endophthalmitis was established, the inflammatory reaction was so intense that the retina was destroyed even though the infection was controlled.²² Similarly, the other study reported no beneficial effect with adjunctive IVT dexamethasone given after 6 hours of endophthalmitis.²³ Even more concerning, when therapy was initiated 12 hours of having endophthalmitis, there was a failure to eradicate bacteria in eyes receiving the combination therapy compared to eyes receiving antibiotic alone.²³ There was treatment failure in all groups when therapy was initiated after 18 hours.²³

The role of IVT dexamethasone in other preclinical endophthalmitis models

Adjunctive IVT dexamethasone was found to have no discernible effect in an experimental model of toxin-producing *Enterococcus faecalis* endophthalmitis.²⁴ On the contrary, for endophthalmitis due to *Streptococcus pneumoniae* and the toxin-nonproducing strain of *E. faecalis*, the combination of dexamethasone and antibiotic appeared to be advantageous over the antibiotic treatment alone.^{16, 24} Delaying dexamethasone by 12 hours after antibiotic treatment did not alter the positive outcomes previously observed.²⁴ However, prophylactic dexamethasone prior to inoculation resulted in increased loss of ERG responsiveness compared to the post-inoculation antibiotics and dexamethasone regimen.²⁴ These findings validated the importance of the timing of IVT dexamethasone in the treatment of endophthalmitis. Lastly, there was no evidence that IVT dexamethasone impaired anti-yeast activity or enhanced yeast proliferation in *Candida albicans* endophthalmitis.²⁵

IVT corticosteroids other than dexamethasone in preclinical endophthalmitis models

The roles of IVT prednisolone and IVT triamcinolone acetonide in acute endophthalmitis have not been examined as closely as IVT dexamethasone. Two preclinical studies investigated the effect of IVT triamcinolone in *Staphylococcus epidermidis* endophthalmitis. One study found that IVT triamcinolone in the absence of appropriate antibiotics impairs ocular immune response, leading to higher culture-positive rate and higher degree of inflammation.²⁶ However, in the presence of appropriate antibiotics, both studies reported that IVT triamcinolone attenuates the clinical signs of inflammation without impairing the therapeutic effect.^{26–27} Taking this a step further, the second study even found a reduction in pathologic damage associated with adjunctive IVT triamcinolone.²⁷ These results are similar

with those reported in most studies investigating the effect of IVT dexamethasone in addition to IVT antibiotics in *Staphylococcus epidermidis* endophthalmitis.

The effect of IVT corticosteroids in retrospective case series

Non-comparative retrospective case series

In 2 small case series that employed adjunctive IVT triamcinolone acetonide for post-operative or post-traumatic endophthalmitis, the results were similar to those previously reported in other preclinical studies.^{28–29} Obviously, the very small number of patients ($n = 5$ and $n = 14$) and lack of comparison arm did not allow any conclusions to be drawn.

Comparative retrospective case series

In the largest comparative retrospective case series of 250 eyes with post-cataract endophthalmitis, there was no difference in the proportion of patients achieving final visual acuity of 20/40 or better depending on whether adjunctive IVT prednisolone 2.5 mg had been used or not.³⁰ Another large comparative case series of 64 eyes with post-cataract endophthalmitis also found no significant difference in final visual acuity outcomes or the proportion of eyes achieving at least 3 lines of improvement in the presence or absence of IVT dexamethasone.³³ Several smaller case series of endophthalmitis due to *Haemophilus influenza* ($n = 16$),³⁴ *Streptococcus pneumonia* ($n = 27$),³⁵ *Staphylococcus aureus* ($n = 27$),³⁶ *Bacillus* organisms ($n = 31$),³⁷ *Pseudomonas aeruginosa* ($n = 28$)³⁸ and Gram-negative organisms ($n = 52$)⁴ failed to demonstrate a statistically significant difference in visual outcomes in eyes with and without IVT dexamethasone.

Jacobs and colleagues published a retrospective case series of 83 patients with delayed-onset bleb-associated endophthalmitis in which IVT dexamethasone purportedly had a beneficial effect in visual outcomes at 1 and 3 months post-treatment.³⁹ However, there was no view of the fundus in 69% of eyes receiving adjunctive IVT dexamethasone compared to 39% not receiving dexamethasone at presentation.³⁹ Moreover, 41% of patients in the IVT dexamethasone group also underwent pars plana vitrectomy (PPV) compared to 8% in the antibiotics only group.³⁹ Given that PPV can clear the visual axis and lead to improved visual outcomes in the short term, the improvement in visual acuity at 1 and 3 months may be a reflection of the baseline confounding factors rather than a true effect of IVT dexamethasone.

Shah and colleagues published a retrospective comparative case series of 57 patients with post-operative endophthalmitis in which adjunctive IVT dexamethasone led to worse outcomes.⁴⁰ Specifically, while 71% of patients treated with IVT antibiotics alone gained 3 lines of vision, only 45% of those treated with adjunctive IVT dexamethasone achieved the same outcomes ($p = 0.09$, 2-sided Fisher test).⁴⁰ Additionally, mean visual acuity at 3 and 6 months was 20/50 in the antibiotics alone group while it was 20/70 in the adjunctive IVT dexamethasone group ($p < 0.05$, Student's t-test).⁴⁰ This study was criticized for its retrospective nature and lack of consideration for the time interval to treatment as a potential confounding factor.

One of the main concerns regarding the use of adjunctive IVT dexamethasone is its possible deleterious effects if there is an undetected underlying fungal infection. However, this fear may be exaggerated given the evidences presented by Majji and colleagues.⁴¹ In a retrospective review of 20 patients with post-cataract or post-traumatic fungal endophthalmitis who were initially managed with vitrectomy, IVT amphotericin B and oral ketoconazole, no differences in visual outcomes or rates of phthisis bulbi were found whether IVT dexamethasone had been used during surgery or not.⁴¹ It is unclear whether their findings can be generalized to cases managed with needle vitreous biopsy rather than vitrectomy. This study is limited by its retrospective nature, small number of patients (n = 7 in the antifungals only group) and differences in the types of fungi causing endophthalmitis in the 2 comparative groups.⁴¹

The effect of IVT corticosteroids in randomized controlled studies

There are three published randomized controlled studies investigating the role of IVT dexamethasone in acute endophthalmitis. Das and colleagues enrolled 63 eyes of 63 patients with suspected post-operative or posttraumatic bacterial endophthalmitis.⁴² All the patients were treated with vitrectomy within 8 hours of presentation which also included a lensectomy or removal of intraocular lens (IOL) if visualization was inadequate. All the patients received IVT, subconjunctival and intravenous antibiotics. They were randomized to receive adjunctive IVT dexamethasone (46%) or IVT antibiotics alone (54%).⁴² A statistically significant reduction in inflammation was observed in the adjunctive IVT dexamethasone group at 1 week and 1 month. However, this finding should not be that surprising given that topical corticosteroids were not prescribed to the antibiotics only group following the vitrectomy plus/minus lensectomy or IOL explantation.⁴² The final visual outcomes at 3 months were similar between the adjunctive IVT dexamethasone and the antibiotics only group.

Gan and colleagues investigated the effect of IVT dexamethasone as adjuvant in the treatment of post-operative endophthalmitis.⁴³ The original sample size was 128 patients to allow for 64 patients in each group. However, the trial was terminated prematurely because the study drug, i.e. dexamethasone sodium diposphate, was no longer available. Hence, only 29 patients were enrolled. All patients underwent vitreous biopsy according to the EVS. Forty-five percent of patients were randomized to receive adjunctive IVT dexamethasone, while 55% of patient received antibiotics alone.⁴³ IVT injections of antibiotics with dexamethasone or placebo were repeated after 3–4 days. No statistically significant difference in visual acuity at 3 and 12 months post-treatment was found between the two groups.

Albrecht and colleagues enrolled 62 patients in a randomized controlled study examining the role of adjunctive IVT dexamethasone in presumed bacterial endophthalmitis.⁴⁴ The patients were randomized to receive adjunctive IVT dexamethasone (48%) or placebo (52%). All patients had a vitreous and aqueous tap for cultures in addition to topical antibiotics and topical dexamethasone. There was no statistically significant difference visual outcomes in the short term (at 2 weeks post-treatment) or intermediate term (at 2 - 4 months post-treatment) between the two groups.⁴⁴

Conclusions

Intravitreal dexamethasone, prednisolone and triamcinolone acetonide as adjuncts to IVT antibiotics for the treatment of presumed bacterial endophthalmitis have been examined in various studies. Dexamethasone is by far the most widely studied adjunctive IVT corticosteroid. Preclinical studies reported mixed results as to the effect of IVT dexamethasone on the antibiotic pharmacokinetics in eyes with endophthalmitis. The results are also mixed regarding the effect of IVT dexamethasone on retinal toxicity with some evidences of a harmful effect in more severe cases of endophthalmitis. Moreover, it is still unclear whether IVT dexamethasone has any beneficial effect in sterile endophthalmitis induced by exotoxin alone. The only definite result from these preclinical studies is that the timing of IVT corticosteroid administration may be important at least in endophthalmitis by highly virulent organism such as *Pseudomonas aeruginosa*.

Similarly, most retrospective comparative studies found no effect of adjunctive IVT dexamethasone. The sole study that showed a benefit had methodological flaws that made this conclusion unwarranted.³⁹ Another retrospective comparative study found a harmful effect associated with adjunctive IVT dexamethasone.⁴⁰ None of the 3 randomized controlled studies showed a statistically significant difference in final visual outcomes with the use of IVT dexamethasone.

Currently, there is no well-designed clinical study showing a statistically significant improvement in final visual outcomes when IVT corticosteroids are given as adjuncts. One study even suggested that the use of IVT dexamethasone may result in worse visual outcomes.⁴⁰ It may be that IVT corticosteroids have beneficial effects in certain clinical settings (e.g. post-cataract or delayed bleb-associated endophthalmitis), for certain causative organism(s) or if given early enough after symptom onset. Well-designed, adequately powered and randomized-controlled trials need be undertaken to find any such beneficial effects in these specific settings. At this point in time, the available evidences do not support the routine use of adjunctive IVT corticosteroids in the treatment of acute endophthalmitis.

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