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Early Administration of the Dexamethasone Implant After Anti-VEGF Therapy for the Treatment of Diabetic Macular Edema

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Purpose:
The Protocol I EARLY analysis described three categories of patient responses to anti-VEGF therapy and concluded that maximum response is obtained after three anti-VEGF injections. Furthermore, a post-hoc analysis of non-responders reported that longer duration and greater magnitude of edema results in fewer letters gained. These findings reveal an unmet need in DME management. The purpose of our study is to examine the use of the 0.7mg Dexamethasone Implant to treat patients gaining less than 5 letters with persistent macular edema after receiving 1-3 monthly anti-VEGF injections.

Methods:
Thirty-eight eyes were included in this study. All 38 patients in this retrospective analysis presented with treatment naïve DME confirmed with optical coherence tomography (OCT). After 11%, 8% or 81% of patients received 1, 2 or 3 monthly intravitreal Bevacizumab or Aflibercept injections respectively, subsequent clinical examinations found patients to have persistent fluid on OCT without reaching the minimum 5 letter vision gain threshold. A single intravitreal dexamethasone 0.7mg implant was administered. Main outcome measures included changes in best-corrected visual acuity (BCVA) and central retinal thickness (CRT).

Results:
At baseline, mean BCVA in this patient population was 72.25 (SD=13.36) ETDRS letters and CRT was 439 microns (SD=152.35). After 1-3 anti-VEGF injections, mean BCVA was 61 (SD=11.74) ETDRS letters (p=0.50) and CRT was 377 microns (SD=121.6) (p=0.09). Three months after a single 0.7mg Dexamethasone injection, BCVA improved from 61 to 75 (SD=12.53) ETDRS letters (p=0.007) and CRT was reduced from 377 to 289 microns (SD=47.38), (p= 5.00E-07), suggesting a statistically significant improvement with 0.7mg Dexamethasone administration.

Conclusions:
The DRCR Network Protocol I EARLY analysis revealed that a significant number of DME patients receiving anti-VEGF mono-therapy show a sub-optimal response within the first 12 weeks of therapy. An opportunity may exist to improve outcomes in these patients with early implantation of the 0.7mg Dexamethasone Implant based on the results of this pilot study. Addressing the multifactorial nature of DME in these patients may yield superior outcomes. A larger, prospective study may be warranted to validate this treatment paradigm based on our results.