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Describe MARINA & FOCUS Trails in the management of Wet ARMD. J2009

Anti-VEGF Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in AMD4-6(ANCHOR)

- **Purpose**
- To compare ranibizumab (RBZ) with photodynamic therapy (PDT) with Verteporfin in the treatment of predominantly classic neovascular AMD.

- **Description**
- It was a multicenter, randomized, double-blind, active-treatment–controlled study.
- Patients were randomly assigned into one of three groups:
  1. PDT with verteporfin every three months as needed plus a monthly sham intravitreal injection (n = 143),
  2. 0.3 mg intravitreal RBZ with sham PDT (saline) as needed every three months (n = 140), or
  3. 0.5 mg with sham PDT (saline) as needed every three months (n = 140).

- **Inclusion Criteria**
- Patients with predominantly classic, subfoveal CNV not previously treated with PDT or anti-angiogenic drugs were eligible.

- **Study Measures**
- The primary, intent-to-treat efficacy analysis was at 12 months, with continued measurements to month 24.
- Key measures included the percentage losing <15 letters from baseline visual acuity (VA) score (month 12 primary efficacy outcome measure), percentage gaining > or = 15 letters from baseline, and mean change over time in VA score and FA-assessed lesion characteristics.
- Adverse events were monitored.

- **Results**
- Of the 423 patients enrolled (143 PDT, 140 each in the 2 RBZ groups), 94.3% of those given 0.3 mg of RBZ and 96.4% of those given 0.5 mg lost fewer than 15 letters, as compared with 64.3% of those in the verteporfin group ($P < 0.001$ for each comparison).
- Visual acuity improved by 15 letters or more in 35.7% of the 0.3 mg group and 40.3% of the 0.5 mg group, as compared with 5.6% of the verteporfin group ($P < 0.001$ for each comparison).
- at month 24 the VA benefit from RBZ was statistically significant and clinically meaningful
- At months 12 and 24, RBZ was superior to PDT ($P < 0.0001$) for mean changes in baseline in total area of lesion, CNV area, and total area CNV leakage.
- Month 12 OCT showed greater centre point thickness decrease from baseline with RBZ than with PDT ($P = 0.0003$).
- RBZ benefits over PDT were evident by 3 months (fluorescein angiography) and 7 days (OCT)
- Lower baseline VA score, smaller baseline CNV lesion size, and younger baseline age were associated with greater gain of letters with RBZ treatment and less loss of letters with PDT.

- **Conclusion**
- RBZ administered as monthly intravitreal injections of 0.3 mg or 0.5 mg over a 24-month period was effective, and superior to PDT treatment, in maintaining or improving VA and lesion characteristics inpatients with new onset, predominantly classic subfoveal neovascular AMD.
- Rates of serious adverse events were low.

MARINA (Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular ARMD)

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- **Purpose**
- To evaluate the role of RBZ in the treatment of minimally classic/occult neovascular ARMD.

- **Description**
- At 96 sites in the United States, 716 patients were enrolled in this 2-year, prospective, randomized, double-blind, sham-controlled study of the safety and efficacy of repeated intravitreal injections of RBZ in minimally classic or occult CNV in AMD.
- Eligible patients were randomly assigned in a 1:1:1 ratio to receive monthly:
  1. Sham (n = 238)
  2. 0.3 mg RBZ (n = 238); or
  3. 0.5 mg RBZ (n = 240)
- Injections in the study eye for 24 months.
- Verteporfin PDT was allowed if the CNV in the study eye became predominantly classic.

- **Study Measures**
- The primary efficacy analysis was at 12 months, with continued measurements to month 24.
- The main outcome measures included the percentage losing <15 letters from baseline VA score (month 12 primary efficacy outcome measure), percentage gaining ≥15 letters from baseline and mean change over time in VA score.

- **Results**
- At 12 months, 94.5% of the group given 0.3 mg of RBZ and 94.6% of those given 0.5 mg lost fewer than 15 letters, as compared with 62.2% of patients receiving sham injections
- Visual acuity improved by 15 or more letters in 24.8% of the 0.3 mg group and 33.8% of the 0.5 mg group, as compared with 5.0% of the sham injection group. The benefit in visual acuity was maintained at 24 months.
- At 12 and 24 months, statistically significant benefits of RBZ over sham treatment were observed for mean change from baseline in the areas of CNV lesion, total CNV, leakage from CNV, SSRD, and disciform scar/ subretinal fibrosis.
- At 12 months (final OCT), the mean change in foveal center point thickness on OCT was a significant decrease in the RBZ group compared with the sham group
- During 24 months, presumed endophthalmitis was identified in five patients (1.0%) and serious uveitis in six patients (1.3%) given RBZ
- The most important predictors of VA outcomes were, in decreasing order of importance, baseline VA score, CNV lesion size, and age.

- **Conclusion**
- The MARINA trial demonstrated that patients treated with RBZ for nonclassic neovascular AMD had substantially better VA outcomes than those who received sham injections.
- In addition, patients treated with RBZ showed stabilization of lesion size in contrast to increases in the sham group.
- These efficacy outcomes were achieved with a low rate of serious ocular adverse events and with no clear difference from the sham-treated group in the rate of nonocular adverse events.