

# خبرنامه الجمن فوق تخصصی ویشره ورتین

آذر ماه ۱۳۹۲ – سال اول – شماره دوم







#### **Breaking Ophthalmology News**

- 1) 31st Annual Meeting of the American Society of Retina Specialists. August 27, 2013
- 2) 13th EURETINA Congress. Presented September 27, 2013.

# **Aflibercept Switch Helps Macular Degeneration**

- Dr. Recchia and colleagues presented results from a series of switch studies at the 31st Annual Meeting of the ASRS.
  - Switching patients to intravitreal aflibercept predictably results in anatomic, but not visual, improvements in patients with wet AMD who have persistent fluid despite treatment with other VEGF inhibitors, new research suggests.
  - Hyung Cho, MD,, presented a retrospective chart review of 353 patients with wet AMD who responded suboptimally to ranibizumab 0.5 mg, bevacizumab 1.25 mg, or both. These patients were then switched to aflibercept 2.0 mg. At 6 months, 64% of aflibercept-treated eyes showed anatomic improvement, and one quarter of them were dry. "Visual acuity did not improve at 1 month or at 6 months.

- In a second retrospective chart review, Ashish Sharma, MD, reported on 93 eyes from 83 patients with neovascular AMD who had previously received multiple injections of ranibizumab or bevacizumab and who still had persistent or recurring macular edema, subretinal fluid, or RPE detachment on OCT. "We saw resolution of fluid in 42% of the eyes. Interestingly, vision improved in 40% of the aflibercept-treated eyes, remained the same in one third of the eyes, and worsened in 27%.
- Eric Nudleman, MD, presented a retrospective review of 8 eyes from 8 patients with wet
  macular degeneration who were treated with monthly ranibizumab for a minimum of 12
  consecutive months. Patients had persistent intraretinal or subretinal fluid and were
  subsequently switched to aflibercept. All patients reported subjective symptoms of
  decreased vision 1 month after the aflibercept injection and Mean central macular
  thickness increased by more than 70%, One month after a single subsequent injection of
  ranibizumab, all patients reported a subjective increase in vision and a return to their
  baseline visual acuity.

#### **Lampalizumab Appears Safe for Dry Macular Degeneration**

The combination of laser therapy plus ranibizumab leads to significantly fewer injections for patients with diabetic macular edema than treatment with ranibizumab alone, according to a prospective study. The combination led to a nonsignificant trend toward better visual acuity. Dr. Kernt presented 12-month study results at the 13th EURETINA Congress. Vision and OCT thickness were similar in the combination and monotherapy groups. However, with the combination, "the retreatment rates are significantly reduced — by more than 50%. Although in previous studies conventional lasers have shown no additional benefit when combined with a ranibizumab regimen, Dr. Kernt theorized the navigated laser (the Navilas navigated photocoagulation laser system )might make a difference. After 66 patients with diabetic macular edema received a loading phase of 3 monthly ranibizumab injections, they were assigned to receive either combination treatment with navigated laser therapy plus ranibizumab (n = 34) or ranibizumab monotherapy (n = 32). "What was significantly different was that 65% of the combination group did not need retreatment for 1 year, compared with 16% of the monotherapy group.

## Oral Pazopanib May Improve Vision, Retinal Thickness

Oral pazopanib (15 mg) was well-tolerated and associated with improvements in visual acuity, central retinal lesion thickness, and central retinal thickness in some patients with wet AMD. "Pazopanib is a potent antiangiogenic that inhibits the same pathway as the intravitreal VEGF standard of care by inhibiting the receptor instead [of] inhibiting the ligand. To determine a suitable dose of oral pazopanib for further investigation in AMD, the investigators conducted a 14-day, placebo-controlled, dose-rising study (5 - 30 mg daily) in 72 healthy participants. They also performed a 28-day, phase 2a open-label

- study of 15 mg oral pazopanib daily in 15 patients with subfoveal CNV secondary to AMD. Study endpoints included safety, pharmacokinetics, BCVA, central retinal lesion thickness, and central retinal thickness at day 29.
- Before day 29, 6 of 15 patients needed rescue therapy, and all of these patients had the CFH Y402H CC "high-risk" genotype for AMD. This group lost 5 letters of visual acuity during the study and had no mean decrease in macular edema.
- The remaining 9 patients completed the study without need for rescue therapy, with improvements from baseline in BCVA (8 ETDRS letters), central retinal lesion thickness ( $-50.94 \mu m$ ), and central retinal thickness ( $-50.28 \mu m$ ).

#### VIVID, VISTA 1-Year Results Show Aflibercept Superior to Laser for DME

- In two phase 3 trials of aflibercept for the treatment of DME, aflibercept-treated groups demonstrated significant and robust superiority of BCVA endpoints over laser photocoagulation at 1 year, according to the results of VIVID-DME and VISTA-DME, presented by Ursula Schmidt-Erfurth, MD, at the Euretina Congress.<sup>1</sup>
- A total of 406 patients were enrolled in VIVID and 466 in VISTA, 2 randomized, multicenter, double-masked phase 3 studies in patients with CSME with central involvement and ETDRS BCVA 20/40 to 20/320. Patients were randomized 1:1:1 to receive 2 mg aflibercept every 4 weeks (2q4) plus sham laser, 2 mg aflibercept every 8 weeks after 5 initial monthly doses (2q8) plus sham laser, or laser photocoagulation plus intravitreal sham treatment.
- The primary endpoint was defined as the change from baseline in BCVA (change in ETDRS letter score) at week 52

#### **Ocular NSAID Reduces Macular Edema After Cataract Surgery**

The use of a topical ocular NSAIDs before and after cataract surgery leads to meaningful reductions in postoperative macular edema in patients with pre-existing retinopathy, new research shows. Nepafenac ophthalmic suspension 0.1% improved outcomes, compared with placebo, in preventing macular edema and maintaining visual acuity in patients with diabetic retinopathy after cataract surgery."Dr. Singh presented the findings at the 31st Annual Meeting of the ASRS. The 130 patients in the nepafenac group received 1 drop of 0.1% three times prior to surgery, on the day of surgery, and then daily for 90 days after surgery. As a primary outcome measure, the investigators assessed the percentage of patients who developed macular edema in the 90 days after cataract surgery

#### Alimera Sciences Receives Complete Response Letter for Iluvien

• In a complete response letter to Alimera Sciences Inc., the FDA stated that the company's new drug application for Iluvien (fluocinolone acetonide implant) could not be approved due to concerns regarding the benefit-to-risk and safety profiles of the intravitreal implant, according to a news release. The FDA indicated that Alimera would need to submit results from a new clinical trial, with at least 12 months of follow-up for all enrolled patients. "The FDA's decision to not approve Iluvien at this time is disappointing not only to us, but also to retinal specialists and DME patients in the US, but we will continue to work with the FDA, through the advisory committee, to determine whether there is a path forward in the [United States] for Iluvien," Dan Myers, President and CEO of Alimera Sciences, said in the news release.

## **INTREPID Trial Radiotherapy Safe for Macular Degeneration**

- Stereotactic radiotherapy, which significantly reduced the need for anti VEGF injections
  in patients with AMD at 12 months, appears to be safe, according to 2-year data from
  the INTREPID trial. Dr. Jackson presented the findings at the 13th EURETINA Congress. In
  the double-masked, sham-controlled study, investigators from 21 sites in Europe
  evaluated participants with neovascular AMD.
- Each patient received a 0.5 mg intravitreal injection of ranibizumab at baseline and monthly injections as required for 12 months. After that, they returned to usual care.
- At baseline, 226 participants were randomized to receive radiotherapy 16 or 24 Gy with the IRay stereotactic radiation system (Oraya Therapeutics) or sham radiotherapy. At 24 months, some subtle microvascular abnormalities were observed. Treatment was associated with a significant 25% reduction in the number of anti-VEGF injections over 2 years.

#### **Monthly Ranibizumab Improves Diabetic Retinopathy**

- The severity of diabetic retinopathy is more likely to improve and progression to PDR is less likely to occur when DME is treated with monthly ranibizumab, new research shows. At 36-month follow-up, vision and the severity of diabetic retinopathy were significantly more likely to have improved in patients treated with monthly ranibizumab than in those treated with a sham injection.
- In addition, ranibizumab-treated patients were approximately 3-fold less likely to develop PDR than their sham counterparts.
- The results were presented by Lloyd Clark, MD, at the 31st Annual Meeting of the ASRS. In the phase 3 RISE and RIDE trials, patients with DME were randomly assigned to

ranibizumab — either 0.3 mg or 0.5 mg monthly — or sham injections. At month 24, patients who had previously received sham injections were crossed over to ranibizumab 0.5 mg monthly. "Ranibizumab improved vision in DME patients through 36 months. After crossover from sham injections to monthly ranibizumab, the mean change BCVA remained relatively stable for the 2 ranibizumab groups and improved by a mean of 4.5 letters for the sham injection group.

• The severity of diabetic retinopathy was also significantly more likely to improve with either dose of ranibizumab than with sham injection.

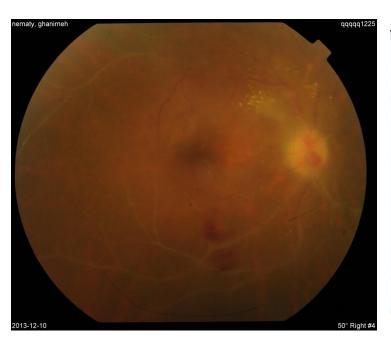
# Ophthalmology Volume 120 Issue12 December 2013 (Pages 2573-2579 ) Soren S.Bierrum MD,, Kim L Mikkelsen MD

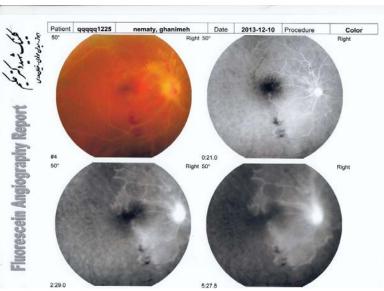
در مطالعات گذشته ریسک RD در جمعیت عمومی حدود یک مورد در ۱۰۰۰۰ نفر در سال گزارش شده بود. ایس خطر به دنبال عمل کاتاراکت حدود ۱۰۰ برابر افزایش می یافت به طوری که ریسک RD به دنبال عمل کاتاراکت را یک مورد در ۱۰۰ نفر گزارش شد. در مطالعه اخیر زمانیکه ریسک RD در دو چشم یک نفر مقایسه شد بطوری که یک چشم تحت عمل کاتاراکت قرار گرفت و با چشم مقابل همان فرد که تحت عمل کاتاراکت قرار نگرفته مقایسه شد. این خطر حدود ۴/۲۳ برابر گزارش شد. به این ترتیب زمانی که بسیاری از فاکتورهای اپیدمیولوژیک مثل سن، جنس و فاکتورهای زمینه ای ژنتیکی که برای هر فرد متفاوت است به این ترتیب خنثی شد. میزان افزایش ریسک RDبعد از عمل کاتاراکت تنها حدود ۴ برابر افزایش می یابد.

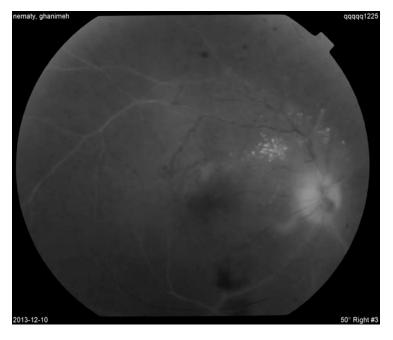
#### Occlusive retinal vasculitis

- 65 years old woman presented with CC of ↓VA OU since 10 months ago.
- Hx of DM 2 since 1 year ago
- Hx of IVB ×3 OS
- VA OD CF4m
- OS HM
- SLE OD: 1+ NVI ,and 3+ cataract ,2+ flare, 1+ cell
- OS: 2+ corneal edema ,extensive NVI ,ectropion uvea,2+ cell and flare
- IOP OD 25
- OS 60

- Funduscopy OU: extensive retinovascular occlusion ,retinal hem, no significant exudation
- FFA: extensive capillary nonperfusion with some vessel wall staining ,ONH leakage
   OD

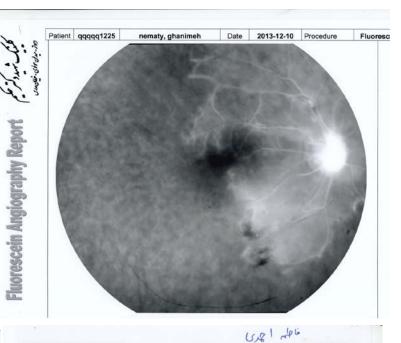


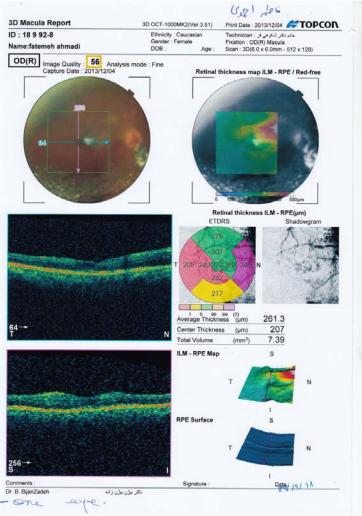


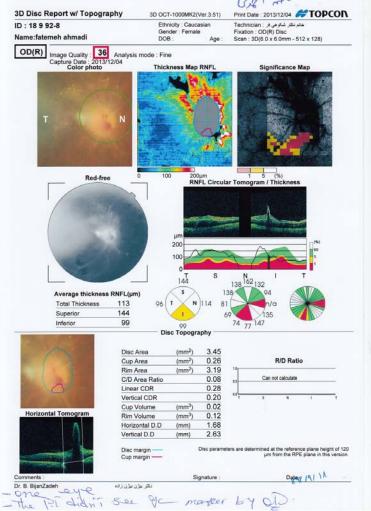












- 1) What is your DD?
- 2) What is your diagnostic and therapeutic plan?

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