Bromfenac May Provide Added Efficacy Over Ranibizumab Alone for AMD

A pilot study suggests that the topical nonsteroidal anti-inflammatory eye drop bromfenac 0.09% (Xibrom, Ista Pharmaceuticals Inc.), administered twice daily, may have an additive effect when used with intravitreal ranibizumab injection (Lucentis, Genentech) in reducing retinal thickness in neovascular AMD.1

In the prospective, open-label, interventional, phase 2 study, 30 eyes were tested consecutively and randomized 2:1 to receive combination therapy (intravitreal ranibizumab and topical bromfenac) or ranibizumab alone. All patients received ranibizumab therapy monthly for 4 months, then as needed monthly in accordance with standard of care. Patients received bromfenac self-administered 1 drop twice a day for 12 months. Three-quarters of subjects had preexisting minimally classic or occult neovascular AMD and a history of ranibizumab use.

No statistically significant differences in visual acuity outcomes were reported at month 12 between the combination group and the group receiving ranibizumab alone, but there was a baseline imbalance, with the combination group having worse vision upon entry. The mean 12-month change in central macular thickness in the combination group was -81.56 µm, compared to -42.50 µm (P = .03) in the ranibizumab-alone group.

"A growing body of clinical data suggest bromfenac may be a safe and effective adjunct therapy to intravitreal injections for age-related macular degeneration," Timothy R. McNamara, PharmD, Vice President of Clinical Research and Medical Affairs of Ista Pharmaceuticals, said in a news release. "We expect to conduct additional analysis of the findings and plan to discuss with the [US Food and Drug Administration (FDA)] the best means, including possible clinical testing, to validate bromfenac’s use in this indication. Our goal is to make a determination about a potential path forward by the first part of next year.”


Human Embryonic Stem Cell Trial for Stargardt to Begin in Europe

A clinical trial for Stargardt macular dystrophy using retinal pigment epithelium derived from human embryonic stem cells (hESCs) has received clearance to proceed from drug regulators in the United Kingdom.

Advanced Cell Technology also recently announced the treatment of the first 2 patients in a phase 1/2 clinical trials for Stargardt macular dystrophy and dry AMD with hESC-derived retinal pigment epithelium cells in the United States. Both patients successfully underwent the outpatient transplantation surgeries, according to the company.

Vitamin D Not Associated With AMD

No association was detected between vitamin D levels and the presence of age-related macular degeneration (AMD), according to a study published in Eye.1

Shani Golan, MD, of Tel Aviv University in Israel, and colleagues obtained data from 1045 patients with AMD and 8124 patients without AMD, all aged 60 years or...
older, who had vitamin D levels measured routinely between 2000 and 2008. The main outcome measure was serum 25-OH vitamin D levels.

The mean (standard deviation) level of 25-OH vitamin D was 24.1 ±9.41 ng/mL (range, 0.8-120) for patients with AMD and 24.13 ±9.50 ng/mL (range, 0.0-120) for those without AMD. One-third (33.6%) of the patients with AMD and 32.86% of those without AMD had a 25-OH vitamin D level less than 16 ng/mL. The percentage of tests in which the 25-OH vitamin D level was greater than 74 ng/mL was 0.19% in patients with AMD and 0.14% in patients without AMD.

“No association was detected between vitamin D levels and the presence of AMD in this cross-sectional study,” the researchers concluded. “These results raise some doubt about an association between reduced vitamin D levels and the prevalence of AMD.”


**Visual Acuity Did Not Differ Among Techniques Used for Retinal Detachment Repair**

Postoperative visual acuity at 1 year did not differ among 4 methods of primary retinal detachment repair, including scleral buckling, vitrectomy, combined scleral buckling and vitrectomy, and pneumatic retinopexy surgery, according to a study in *Retina.*

Shlomit Schaal, MD, PhD, of the University of Louisville, KY, and colleagues conducted a retrospective, interventional, comparative case series of 1226 patients with primary retinal detachment. All patients completed 1-year follow-up and were divided into 4 groups based on method of repair: scleral buckling surgery (n=322), pars plana vitrectomy surgery (n=442), a combination of scleral buckling and vitrectomy surgery (n=316), and pneumatic retinopexy surgery (n=56). Reattachment success rates, pre- and postoperative visual acuity, complications, and change in refractive error were assessed.

The initial success rate for retinal reattachment was 86% for scleral buckling only, 90% for vitrectomy only, 94% for a combination of scleral buckling and vitrectomy, and 63% for pneumatic retinopexy surgery. Patients who underwent pneumatic retinopexy surgery had a lower initial success rate, but there was no statistically significant difference in initial reattachment rates among the other 3 groups. Furthermore, there was no statistically significant difference in final visual acuity among the 4 groups. Complication rates varied among the techniques used, the investigators concluded.


**Frequent Aspirin Use May Be Associated With AMD**

Frequent aspirin use may be associated with early AMD and wet late AMD, according to a study published in *Ophthalmology.*

Paulus T.V.M. de Jong, MD, PhD, of The Netherlands Institute for Neuroscience and Academic Medical Center in Amsterdam, and colleagues analyzed data from 4691 patients who were enrolled in the population-based, cross-sectional European Eye Study. All participants were aged 65 years and older and were collected by random sampling. Aspirin intake and potential confounders for AMD were determined via a questionnaire, and ophthalmic and basic systemic measurements were performed in a standardized way. AMD was classified using fundus images graded according to the International Classification System. Nonfasting blood samples were analyzed in one laboratory, and associations were analyzed by logistic regression.

Early AMD was present in 36.4% of patients, and late AMD was present in 3.3% of patients. Monthly aspirin use was reported by 1931 participants (41.2%), once-weekly aspirin use by 7% of participants, and daily use by 17.3% of participants. For daily aspirin users, the odds ratios (adjusted for potential confounders) showed a steady increase with increasing severity of AMD grades: grade 1, 1.26 (95% confidence interval [CI], 1.08–1.46; P < .001); grade 2, 1.42 (95% CI, 1.18–1.70); and wet late AMD, 2.22 (95% CI, 1.61–3.05).

“Frequent aspirin use was associated with early AMD and wet late AMD, and the [odds ratios] rose with increasing frequency of consumption,” the study authors concluded. “This interesting observation warrants further evaluation of the associations between aspirin use and AMD.”

Gas Endotamponade After Microincision Vitrectomy May Reduce Risk of Endophthalmitis

Gas endotamponade after microincision sutureless vitrectomy may reduce the risk of postoperative endophthalmitis, according to a study in *Retina*.1

Allen Chiang, MD, of East Bay Retina Consultants in California, and colleagues conducted a collaborative, multicenter, retrospective chart review of 2336 eyes that underwent microincision sutureless vitrectomy (23 or 25 gauge) with either SF₆ or C₃F₈ gas endotamponade for macular hole between January 2008 and December 2009. The search methodology was structured to identify the main outcome measure: the occurrence of acute postoperative endophthalmitis (less than 6 weeks after pars plana vitrectomy).

Over a 2-year period, 1 eye (0.04%) had postoperative endophthalmitis. All eyes had near-complete gas-fluid exchange at the end of surgery. C₃F₈ was the most common endotamponade agent used, and the majority of cases were performed with 23-gauge vitrectomy. No other complications were observed.

"Endophthalmitis was a rare occurrence in this large series of gas-filled eyes after macular hole surgery (0.04%)," the study authors wrote. "Gas endotamponade after microincision sutureless vitrectomy may be beneficial in reducing the risk of postoperative endophthalmitis; however, additional studies are necessary to make a definitive recommendation."


Combined 23-Gauge Vitrectomy, Phacoemulsification Was Safe, Effective in PDR

Combined 23-gauge sutureless vitrectomy and clear corneal phacoemulsification was safe and effective in patients with proliferative diabetic retinopathy (PDR), according to a study in *Retina*.1

Dae Yeong Lee, MD, of Gachon University of Medicine and Science in Korea, and colleagues conducted a retrospective, consecutive, noncomparative, interventional case series of 136 eyes of 108 patients who underwent combined sutureless vitrectomy and clear corneal cataract surgery for the complications of PDR. The primary outcome measures were visual outcomes and surgical complications.

Main indications for the combined surgery were vitreous hemorrhage (78 eyes; 57.4%) and tractional retinal detachment (36 eyes; 28.7%). The logarithm of the minimum angle of resolution visual acuity improved from 0.86 ±0.59 preoperatively to 0.39 ±0.52 at 6 months postoperative (P < .0001). Seven eyes (5.1%) had intraoperative retinal tears, and postoperative vitreous hemorrhage occurred in 10 eyes (7.5%). One eye (0.7%) had postoperative hypotony (<6 mm Hg). During the 6 months after combined surgery, 1 eye (0.7%) developed neovascular glaucoma, and 6 eyes (4.4%) required a repeat vitrectomy, of which 3 were for retinal detachment and 3 were for vitreous hemorrhage.

"Combined 23-gauge sutureless vitrectomy and clear corneal phacoemulsification in patients with [PDR] was safe and effective," the study authors wrote. "It may have not only the known advantages of conventional combined surgery but also additionally those such as faster visual rehabilitation and less conjunctival fibrosis."


Bevacizumab Pretreatment May Be Effective in Vitrectomy for Severe DR

Pretreatment with intravitreal bevacizumab (Avastin, Genentech) in vitrectomy may help improve outcomes for severe diabetic retinopathy (DR), according to a study in the *British Journal of Ophthalmology*.1

Li-Quan Zhao, MD, of Xinhua Hospital in Shanghai, and colleagues conducted a comprehensive literature search to identify randomized, controlled trials and comparative studies of vitrectomy with or without bevacizumab pretreatment for severe or complicated DR. The investigators performed meta-analyses for intraoperative outcome parameters (intraoperative bleeding, endodiathermy, iatrogenic retinal tears, and mean surgical time) and postoperative outcome parameters (best corrected visual acuity [BCVA], recurrent vitreous hemorrhage, reabsorption time of blood, and other complications).

Overall, 6 trials and 1 study were used for comparing vitrectomy alone (142 eyes, control group) with vitrectomy with intravitreal bevacizumab pretreatment (139 eyes). Incidence of intraoperative bleeding and frequency of endodiathermy were statistically significantly less in patients who were pretreated with bevacizumab compared with those who were not ($P < .01$). The bevacizumab-pretreatment group also required significantly less surgical time than the control group ($P = .003$). Postoperative outcomes showed that blood reabsorption time was significantly shorter ($P = .04$), incidence of recurrent vitreous hemorrhage was insignificantly less ($P = .05$), and final BCVA was significantly better ($P = .003$) in the bevacizumab-pretreatment group. Other complications were not statistically significant.

“[Intravitreal bevacizumab pretreatment] in vitrectomy can achieve excellent clinical outcomes for severe [DR],” the study authors wrote. “It potentially facilitates surgeons’ [maneuvers] and reduces intra- and postoperative complications.”

Bioptigen Awarded Research Grant for Pediatric Spectral Domain OCT Systems

Bioptigen Inc. (Research Triangle Park, NC) has been awarded a $2.7 million, 27-month grant from the National Eye Institute for the research of spectral domain optical coherence tomography systems targeted to the needs of children, according to a company news release.

“It is both exciting and satisfying to work on imaging tailored to the developing eye. Our objective is to provide researchers and clinicians with the comprehensive, mobile imaging they require to properly view and manage pediatric eye disease,” Eric L. Buckland, PhD, president and CEO of Bioptigen, said in the news release.

The goal of the research is to enable structural and functional imaging of premature and neonatal infants using a compact, hand-held device, according to Bioptigen. The Bioptigen Envisu spectral domain ophthalmic imaging platform employs low-power incoherent light to generate high-resolution, depth-resolved images of ocular tissues. Envisu rapidly acquires and displays volumetric images suitable for real-time exploration of tissue physiology and pathology.

Canon Extends Range of Digital Retinal Cameras With CR-2 Plus

Canon Europe has announced the availability of the CR-2 Plus, a nonmydriatic retinal camera with fundus autofluorescence capabilities. Incorporating Canon EOS digital SLR technology, the nonmydriatic retinal camera is an 18-megapixel digital camera adapted specifically for ophthalmic photography, a company news release said.

The CR-2 Plus works with the widest range of ISO settings so that eye care professionals can choose to use very low ISO speeds to attain the best possible image without compromising quality. The low flash mode in combination with higher ISO values will not cause the pupil to constrict after the flash, allowing images to be taken again in quick succession, according to Canon.

The CR-2 Plus provides the option to connect to hospital networks and practice management systems and is fully DICOM compliant.

Iluvien FDA Decision Due November 12

The FDA notified Alimera Sciences it will not require an advisory committee as part of its 6-month resubmission review of Iluvien (fluocinolone acetonide) in the treat of diabetic macular edema. The Prescription Drug User Fee Act (PDUFA) date is set for November 12, 2011.

In December 2010, the FDA issued a Complete Response Letter (CRL) to Alimera regarding its New Drug Application for Iluvien in the treatment of diabetic macular edema, which included data through month 24 of the FAME Study. Alimera submitted a response to the FDA in May 2011, addressing issues raised in the CRL. The FDA classified Alimera’s response as a Class 2 resubmission, resulting in a 6-month review period and PDUFA date of November 12, 2011. In July 2011, the FDA said an advisory committee would not be called during this review.

“We believe that we have met all clinical endpoints for Iluvien and that our data supports the FDA’s efficacy and safety requirements,” said Dan Myers, Alimera’s president and CEO, “and we look forward to continuing to work with the FDA toward the approval of Iluvien.”