RETINA ASSOCIATES

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Larzo Documents Treatment of Rare EFE

Cris Larzo, M.D., SERA physician, is the senior author and faculty physician, with five colleagues, who co-wrote an article that appears in the February 2012 issue of *The International Journal of Clinical Ophthalmology and Visual Sciences*. The article describes diagnosis and treatment of endogenous fungal endophthalmitis, or EFE, a rare complication of disseminated fungal infection, or candida endophthalmitis, that generally has a poor prognosis and can result in blindness.

Cris Larzo, M.D.

The condition is difficult to diagnose, sometimes mimicking ailments that are more common and thereby engendering delays in treatment. Some studies say misdiagnosis of candida endophthalmitis is close to 50 percent, the article reports.

A compromised immune system, serious chronic diseases, malignancies, IV drug use, and intravenous catheters are some of the underlying sources for the infection. Microorganisms then migrate through the blood stream to the retina and choroid. Care is complicated for EFE patients because treatment is toxic antifungal therapy.

In the recent article, Dr. Larzo and his co-authors who were ophthalmology and pathology colleagues at West Virginia Eye Institute in Morgantown, report a case in which the infection was successfully treated with

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R. Keith Shuler, Jr., M.D., Joins SERA in June

R. Keith Shuler, Jr., M.D., began seeing SERA patients in June 2012, when he and his family moved to Knoxville. Dr. Shuler previously practiced for five years at Carolina Eye Associates in Southern Pines, NC.

"I met Nick Anderson, who is a current SERA physician, when we worked together at Emory University. I wasn't looking for a change, but he suggested I consider moving my practice and my family to Knoxville. As my wife and I explored the possibilities, we reasoned that a larger university town would have more to offer our children who are 2, 4, 6, and 8 now. I'm really excited about the opportunity to work at SERA and live in East Tennessee."

Amy Shuler, Keith's wife, holds a master's degree in elementary and special education. She was actively involved in their North Carolina schools, serving on school board committees and teaching at Sandhills Community College.

R. Keith Shuler, Jr., M.D.

Dr. Shuler says, "My goal as a doctor is to treat every patient as family. Keep that in your heart, and I believe you will do the right thing for patients."

Dr. Shuler is originally from Atlanta, GA. In 1994, with highest distinction, he earned the B.S. in Biology, with a minor in Business Administration from the University of North Carolina, Chapel Hill. He graduated from Emory University School of Medicine, Atlanta, in 1998. From there he accepted a two-year surgery residency and internship at the University of Virginia

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at Charlottesville. He moved on to an ophthalmology residency and a post-doctoral fellowship in molecular biology and genetics of the retina at Emory University School of Medicine from 2000 to 2005.

He was awarded the prestigious Heed Fellowship during his clinical fellowship in vitreoretinal disease and surgery at Duke University, Durham, NC, from 2005 to 2007. The Heed Fellowship is highly regarded in the field, as there are only a handful of recipients each year throughout the U.S.

Dr. Shuler was selected as one of four residents and/or fellows in the country to present his research at the Association of University Professors of Ophthalmology Meeting in 2005. His research interests focus on possible genetic treatments for retinal diseases.

He was awarded the 2006-2007 Hornaday Award as the top fellow at Duke Eye Center – an award given for excellence in clinical care, ethics, and research. ❑

Treatment of Rare EFE

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intravitreal amphotericin B and systemic fluconazole. They describe the unusual case of EFE in a young man whose troubles likely began with a nail fungus. As an immunocompetent patient, his case was rare and the first of its kind reported in North America. Most patients who contract this disease have debilitating diseases such as leukemia, end-stage liver disease, or HIV, so they are at higher risk than patients whose immune systems are functioning normally.

Dr. Larzo's patient was first seen by an outside optometrist who referred him to the Eye Institute physicians. The patient complained of eye redness, light sensitivity, pain, floaters, and blurred vision in his left eye.

The patient later admitted to IV drug use which greatly increased the chance of the nail fungus spreading to his eye. The article describes the intricate, step-by-step process of diagnosing the patient and consequent varieties of drugs used to isolate the infection and stop the damage to his vision. Interestingly, Dr. Larzo says that just a couple of months ago another similar case was been reported in that location, so there may be a unique strain of the fungus circulating in that part of WV.

You may read an abstract of the article online at the National Center for Biotechnology Information (a division of the National Institutes of Health) where you also will find links to various subscription-based sites to download or read the full article. The NCBI URL is http://www.ncbi.nlm.nih.gov/pubmed/22222717

Dr. Larzo and his co-authors were colleagues when he served his residency in the Department of Ophthalmology at WVU Eye Institute. More than a year ago, Dr. Larzo joined SERA in the Kingsport office. He was already acquainted with another WVU colleague, Allan Couch, a Kingsport SERA physician who joined the practice in 2002.

"It was a difficult decision to relocate my practice from West Virginia," Dr Larzo says, "but I've been totally satisfied with the move.

"I can't imagine its going any better. My philosophy of patient centered practice fits perfectly with the SERA vision. The staff treat me like gold, and the patients have been warm and welcoming."

Dr. Larzo and his wife, a pediatrician, are rearing their three young children in Johnson City. They enjoy the outdoors in scenic East Tennessee, and are active in Grace Fellowship Church. Read more about Dr. Larzo and other SERA vitreoretinal surgeons on the SERA website at http://tennesseeretina.com/physicians.htm❑

Research Trials

Below are descriptions of clinical trials in progress (enrolling or following) at SERA's East Tennessee locations. Patients or referring physicians may ask about requirements for participating by calling the SERA Clinical Trials Coordinators:

Knoxville – Kristina Oliver, 865-579-3999
Tri-Cities – Deanna Long, 423-782-1327

Knoxville

DRCR.NET

Diabetic Retinopathy Clinical Research Network (DRCR.net) facilitates multi-center clinical research of Diabetic Retinopathy, Diabetic Macular Edema, and associated conditions. Genetic material collected provides an opportunity to combine data from multiple populations, including the Type 1 and Type 2 diabetics in the U.S., to define genetic factors that confer risk for development and progression of diabetic retinopathy, and response to therapeutic intervention. The database may also help to assess genetic susceptibility and resistance to DR and also variants impacting visually-important biomarkers for MD and neovascularization. The studies are funded by the National Eye Institute,

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Research Trials

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of the federal National Institutes of Health. Read more at DRCR.net.

Protocol I – Intravitreal Ranibizumab or Triamcinolone Acetonide in combination with Laser Photocoagulation for Diabetic Macular Edema. *In progress/enrollment closed.*

Protocol R – A Phase II evaluation of topical NSAIDs in eyes with non-central Involved Diabetic Macular Edema. *Enrolling.*

Protocol S – Prompt Panretinal Photocoagulation versus Intravitreal Ranibizumab with deferred Panretinal Photocoagulation for Proliferative Diabetic Retinopathy. *Enrolling.*

Protocol T – Bevacizumab versus Ranibizumab versus Eyelea for Diabetic Macular Edema. *Enrollment scheduled to start Fall 2012.*

Genes in Diabetic Retinopathy Project – Blood sample collection and submission to the DRCR Genetic Repository. *For enrolling patients who are currently enrolled in an applicable DRCR study.*

AREDS2

The Age-Related Eye Disease Study 2 (AREDS2) is a multi-center, randomized trial designed to assess the effects of oral supplementation of macular xanthophylls (Lutein and Zeaxanthin) and/or long-chain omega-3 fatty acids (Docosahexaenoic Acid, or DHA and Eicosapentaenoic Acid, or EPA) on the progression to advanced Age-related Macular Degeneration (AMD). The study also will assess whether forms of the AREDS nutritional supplement with reduced zinc and/or no beta-carotene works as well as the original supplement in reducing the risk of progression to advanced AMD. AREDS2 researchers and others will use this material to look at causes of eye disease, using genetic materials (DNA). Read more at areds2.org.

Age-Related Eye Disease Study 2 (AREDS2) – Multi-center, randomized trial of Lutein, Zeaxanthin, and Omega-3 Long-Chain Polyunsaturated Fatty Acids (DHA and EPA) in Age-Related Macular Degeneration. *In progress/enrollment closed.*

AREDS2 Genetics Study – Blood and saliva sample collection and submission to the Age-Related Eye Disease Study 2 Genetic Repository. *Now enrolling patients who are currently enrolled in the AREDS2 study.*

AREDS2 Sirolimus Study – Multi-center, randomized, single masked Phase 2 Study of Intravitreal Sirolimus in the treatment of Central Geographic Atrophy associated with Age-Related Macular Degeneration. *Enrollment scheduled to start July 2012.*

Tri-Cities

THROMBOGENICS TG-MV-005

ThromboGenics TG-MV-005 is a randomized, sham injection controlled, double masked, multi-center trial of Ocriplasmin Intravitreal Injection for treatment of Focal Vitreomacular Adhesion in subjects with exudative Age-Related Macular Degeneration. Read more at clinicaltrials.gov. *Enrollment ended, still in follow up.*

DRCR.NET

Diabetic Retinopathy Clinical Research Network (DRCR.net) facilitates multi-center clinical research of Diabetic Retinopathy, Diabetic Macular Edema, and associated conditions. Genetic material collected provides an opportunity to combine data from multiple populations, including the Type 1 and Type 2 diabetics in the U.S., to define genetic factors that confer risk for development and progression of diabetic retinopathy, and response to therapeutic intervention. The database may also help to assess genetic susceptibility and resistance to DR and also variants impacting visually-important biomarkers for MD and neovascularization. The studies are funded by the National Eye Institute, of the federal National Institutes of Health. Read more at DRCR.net.

Protocol R – A Phase II Evaluation of Topical NSAIDs in Eyes with Non Central Involved Diabetic Macular Edema. *Enrolling.*

Protocol S – Prompt Panretinal Photocoagulation versus Intravitreal Ranibizumab with Deferred Panretinal Photocoagulation for Proliferative Diabetic Retinopathy. *Enrolling.*

Protocol T – Bevacizumab vs Ranibizumab versus Eyelea for Diabetic Macular Edema. *Start up scheduled for Fall 2012.*

GENES IN DIABETIC RETINOPATHY PROJECT

To be eligible, a patient must be enrolled currently in an applicable DRCR.net study or previously been enrolled in an applicable DRCR.net study. The Network will prioritize the genetic repository database of clinical phenotypes and genotype information to create the initial bioresource using criteria set from several high priority research topics. Read more at DRCR.net.

During or after completion of the genetic repository database, separate statistical analysis plans will be developed for each DRCR.net topic of interest. The topics are not limited to, but may include any or all of the following.

1. Pharmacogenomic studies – Study participants who have a good response to treatments shown to

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SOUTHEASTERN RETINA ASSOCIATES

New Morristown Office Flourishes

Last August, SERA celebrated opening its first free standing office built from the ground up and dedicated to serving only SERA patients in Morristown.

Pam Gerace is the building manager. She says the spotlight is on how much space is now available to accommodate a sizable number of SERA patients who live in the Morristown area. SERA's seven Knoxville vitreoretinal surgeons come to the location at different times during the week, sharing patient responsibilities. The practice averages 50 to 60 patient appointments per doctor per day.

Gerace says the new location is a real service to many SERA Morristown patients who are physically challenged and who are spared the trip all the way to Knoxville. "We are so proud to expand retinal care to so many patients. The need is so great," she says.

SERA's physicians bring their own staffs with them to the new office, including their schedulers. State of the art computer communications technology connects all nineteen SERA offices throughout East Tennessee and in neighboring states. So, patient records, including photos and other diagnostic records, are immediately accessible in every location.

The building is designed for easy access, including automatic doors. The 6000-square-foot building is a contemporary design with emphasis on bringing the outdoors inside. Two spacious waiting areas feature red brick and aluminum, with floor to ceiling window walls. Natural light enhances patient and employee spaces.

Many SERA staff members were instrumental in design, layout, and setup of the office and clinic. Colors, textures, and finishes to complement the architecture were selected from a natural palette in keeping with bringing the outdoors in. The walls in the front waiting room are brick, and the rest of the office is decorated in soft earth tones. Wall art is abstract with red browns and greens. Waiting room chairs and oversized bench seating were selected to create a homey and welcoming feel. Exam rooms are oversized for patient comfort, and office staff appreciate their generous desk and counter space.

SERA's Morristown office has a visible location at 3101 West Andrew Johnson Hwy, across the street from K-Mart and close to Lowe's and the Golden Corral. ❑

Research Trials

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be beneficial compared to those who do not have a good response,

2. Theranostics – Study participants who have a good response initially and then fail to sustain a good response.
3. Rapid versus delayed onset – Study participants with shorter or longer duration of diabetes who develop PDR or DME.
4. Analysis of worsening of diabetic retinopathy – Study participants who develop severe PDR before or despite panretinal (scatter) photocoagulation versus study participants who have not developed any PDR after different durations of diabetes.
5. Analysis of DME worsening – Study participants who develop DME with less or more amounts of thickening versus study participants who have not developed any DME despite different durations of DM.

QRK 202

QRK 202 is an open-label dose escalation study of PF-04523655 combined with a prospective, randomized, double-masked, multicenter, controlled study (Stratum II) evaluating the efficacy and safety of PF-04523655 alone and in combination with Ranibizumab Versus Ranibizumab alone in Diabetic Macular Edema (a MATISSE STUDY). Read more at http://clinicaltrials.gov/ct2/show/NCT01445899. *Enrollment start-up soon.* ❑