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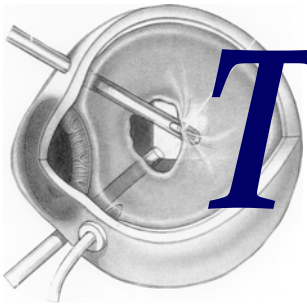

The Light Pipe

The newsletter of Georgia Retina, P.C.

What's Your Diagnosis?

7-Year-Old Girl with Decreased Vision Bilaterally

Initial History

A 7 year old girl presented to the clinic complaining of trouble seeing over the past month. The change in vision was constant, with a steady decline in both eyes. She denies photopsias, trauma, headache, nausea, or vomiting. Her ocular history is unremarkable, with prior visual acuity of 20/20 in both eyes. She had undergone an uncomplicated tympanostomy 2 years ago; otherwise, her medical history is unremarkable. She takes Flintstones vitamins daily. Her family history reveals no known heritable diseases. On a comprehensive review of systems, she states that, over the past several months, she has had occasional spontaneous sweating episodes associated with a cool feeling in her hands and feet. The family has no pets, and has not traveled recently.

ALSO IN THIS ISSUE:

Examination

On examination, she is a healthy-appearing girl in no distress. She is afebrile (98.2 F) with a pulse of 90 and a blood pressure of 110/70. Best corrected visual acuity is 20/70 OD and 20/80 OS. Intraocular pressure is 20 mmHg in both eyes. She has full ocular motility and full confrontational fields to finger counting. Pupils are equal and briskly reactive, with no relative afferent pupillary defect bilaterally. Anterior segments are unremarkable bilaterally.

Posterior segment evaluation of the right eye reveals a clear vitreous cavity with no inflammatory cells. The optic disc is edematous with profuse exudation into the peripapillary region. This exudation extends into the macula, giving the appearance of a macular star. The retinal periphery is unremarkable. The posterior segment of the left eye has a similar appearance, with disc edema and peripapillary exudation extending into the macula. (See **figures 1** and **2**)

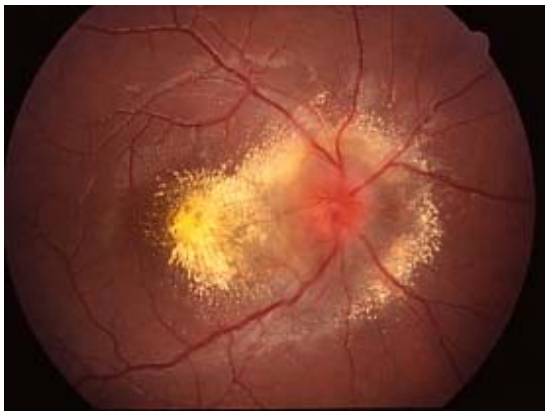

Figure 1.

Figure 2.

Differential Diagnosis

The differential diagnosis in this case includes causes for elevated intracranial pressure, such as a CNS neoplasm, dural sinus thrombosis, or pseudotumor cerebri. A carotid cavernous fistula could also give this fundus appearance, but would likely be accompanied by conjunctival injection. Papillopathy may also result from diabetes mellitus or hypertension. Neuroretinitis often appears as disc edema associated with a macular star. Causes of bacterial neuroretinitis include *Bartonella henselae* (cat scratch disease) and tuberculosis. Lyme disease, syphilis, and leptospirosis are spirochete mediated diseases that may cause neuroretinitis. Toxoplasmosis and viral infections (herpes, varicella, Epstein-Barr, and hepatitis B) may occasionally yield a neuroretinitis as well.

(Continued on page 7)

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The PAT Survey (Preferences And Trends)

With all of the new ground being broken in the specialty of retina, there are many aspects of care where a uniform standard of practice has not yet been established. Innovative treatments, new technology and therapies performed in combination present many options to the vitreoretinal specialist and to our patients. The PAT survey is a survey of the membership of the ASRS (American Society of Retinal Specialists) which is now in its ninth year. The survey is always enlightening and often demonstrates how many ways it is possible to approach a particular problem. In many cases there is a consensus and in others there is clearly not. This pioneering project helps us identify how clinical techniques are evolving and may even reveal controversies that are in need of clinical trials to find evidence proving which of several possible approaches is best.

Some of the findings were interesting. For example, when asked how retinal specialists would like their own juxtafoveal classic choroidal neovascular membrane treated, only less than 5% would want MPS (Macular Photocoagulation Study) style focal laser. Almost 40% would want Avastin and almost 40% would want Lucentis with a little over 17% requesting PDT plus an anti-VEGF inhibitor. Of course the only data from a randomized multicenter trial for this type of lesion is the MPS showing the relative benefit of focal laser. All of the anti-VEGF drugs have been studied for directly sub-foveal lesions but not juxtafoveal lesions. This is an example of how clinical practice can outpace the ability of large studies to demonstrate the benefit of certain treatments that become widely accepted. Another common occurrence is that even when clinical trial data is available, actual practice modifies the protocols. When asked the number of anti-VEGF injections that they give before deciding that a particular treatment is ineffective, 44% of retinal specialists answered three and 38% answered four to six. Fewer than 5% answered seven to nine, but there were answers even up to greater than 12. Of course in the MARINA and ANCHOR studies patients received 24 injections, once per month for two years, suggesting that therapy should be continued regardless of initial effect or lack of it. Of course we really don't yet know the best approach. Another example of this is the treatment of BRVO (branch retinal vein occlusion). When asked about the management of a 3 month old BRVO with macular edema, where the vision had dropped from 20/40 to 20/250 the answers were all over the board. About 1/3 would do grid laser (consistent with the recommendations of the BRVO study) but about 12% would use an anti-VEGF inhibitor, 12% would use intravitreal kenalog, 20% would use laser plus kenalog, and 20% would use laser plus kenalog plus an anti-VEGF drug.

There were 80 questions in the survey and each presents its own interesting scenario which illustrates the variability of clinical practice. We all look forward to a reduction in variability as more data and clinical experience accumulates which will help us toward a clear consensus for optimal management. *-JBS*

ARMD: Evolving Treatment Paradigms for a Complicated Disease

Age-related macular degeneration (ARMD) is becoming a world-wide concern affecting roughly 30 million people worldwide. In the United States, studies have estimated that approximately 3 million individuals will be affected by 2020 and ARMD continues to remain the leading cause of vision loss in Caucasians over the age of 55. About 10-15% of these individuals will have the exudative form of the disease, resulting in dramatic loss of vision and quality of life.

The past decade has spurned tremendous research in this field which has yielded drugs that target choroidal neovascularization (CNV) found in exudative ARMD. Prior to 2000, the only treatment available was thermal laser photocoagulation, based on the finding of the MPS (Macular Photocoagulation Study). This treatment resulted in immediate visual loss when subfoveal CNV was treated. The introduction of Photodynamic Therapy (PDT) with Verteporfin (Visudyne™) in 2000 was welcomed as this treatment theoretically treated subfoveal CNV without damaging the overlying retina. The results of the TAP (Treatment of ARMD with PDT) showed that PDT could decrease progression and limit visual loss.

In 2004, Macugen® (pegaptanib) became the first pharmacologic agent approved by the FDA that targeted specific biologic molecules (i.e. VEGF-165) in the synthesis of abnormal CNV. In 2005, Avastin® (bevacizunab), a full-length, recombinant, humanized, monoclonal antibody, began to gain widespread use and acceptance as a treatment alternative to Macugen. Avastintargets all VEGF-A isoforms, as opposed to only VEGF-165. Despite Avastin being an off-label treatment alternative for exudative ARMD, it is now widely utilized for exudative ARMD based on promising results from several small open-label studies and its cost-effectiveness.

Lucentis® (ranibizumab) was FDA approved in 2006. This drug is a humanized antigen-binding fragment (as opposed to a full-length antibody such as Avastin) designed to also block all active isoforms of VEGF-A. The results of the MARINA (Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular AMD) and ANCHOR (Anti-VEGF Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in AMD) trials have shown Lucentis to be effective and superior to previously FDA-approved treatments for all angiographic subtypes of exudative ARMD. The results from the MARINA and ANCHOR trials recommend monthly injections of Lucentis, which impacts greatly on the lifestyle for our elderly patients in addition to placing a tremendous burdon on healthcare costs. The approval and availability of Lucentis to treat neovascular AMD has not stopped interest in Avastin, because there are considerable cost differences in the two therapies. A Lucentis treatment costs approximately $2,000 per dose while an Avastin treatment for AMD costs approximately $50-$100. Considering that both drugs require multiple treatments, this cost differential is substantial.

In an attempt to drive down drug costs and the number of office visits, several clinical trials helped address these issues. The PIER and PrONTO studies have been performed to understand the necessity of monthly injections. The PIER study was a randomized controlled clinical trial which showed a benefit to quarterly injections, after the initial administration of 3 consecutive monthly injections. Though beneficial, the results were not as robust as in the ANCHOR and MARINA trials which mandated monthly injections. The PrONTO study results closely mirrored these studies, but was not a randomized, controlled, clinical trail and enrolled only 40 patients. The Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) (is a multi-centered randomized clinical trial will assess the relative safety and efficacy of two treatments, Lucentis vs. Avastin, for subfoveal CNV. Enrollment is slated to begin in early 2008.

In clinical practice, retina specialists are realizing that exudative ARMD is a diverse disease with multiple subtypes. There is a definite subgroup of patients that are refractory to VEGF inhibition. Despite multiple intravitreal VEGF inhibitor injections, leakage is still noted on OCT and fluorescein angiography. This concept has spawned interest in utilizing multiple intravitreal drugs, in combination with PDT, to treat CNV. This treatment paradigm is no different to utilizing multiple chemotherapeutic drugs to treat cancers.

Currently, subfoveal CNV secondary to exudative ARMD is treated as one disease entity. Perhaps multiple agents to treat these "subtypes" is required. Drugs that address inflammatory mediators (intravitreal kenalog or dexamethasone), angiogenic factors (Lucentis, Avastin), and vessels refractory to VEGF inhibition (Visudyne-PDT) are now being studied in randomized, controlled, clinical trials such as DENALI and PDEX.

DENALI will examine Lucentis monotherapy versus PDT plus Lucentis. The issue of reducing fluence to 300mW/cm^2 compared to the standard 600mW/cm^2 will also be examined in this randomized, mulit-center, controlled , clinical trial. PDEX is a randomized, multicenter, controlled, clinical trial comparing PDT, intravitreal dexamethasone and Lucentis versus Lucentis monotherapy. Other trials using "triple therapy" are being conducted, substituting Avastin for Lucentis.

As newer therapies evolve, the complex nature of exudative ARMD is becomes more evident. Monotherapy may not be the desired treatment regimen to address this multi-component disease. In the next year or so, the results of combination treatment regimens for exudative ARMD will become available and may, once again, change the way this disease is managed. *-AS*

Avoiding Common Wage and Hour Violations

The Federal Fair Labor Standards Act requires employers to pay employees at least the minimum wage for every hour worked and 1½ times their hourly rate for every hour worked over 40 in a workweek.[1]

- Minimum wage in Georgia is currently $5.85 per hour.
- Employers may not average the employee's time over a pay period. If an employee works 42 hours in a workweek, he/she is entitled to overtime for that week, even if he/she works only 38 hours the next week.

Doctors, independent contractors and bona fide volunteers are specifically exempted from the FLSA.

- An employee cannot "volunteer" to do the same types of duties on behalf of the employer, that he/she is paid to do, even for a charitable event.
- For example, if an LPN "volunteers" at a health day outside the workplace, he/she must be paid for that time. To avoid overtime, you may give the LPN time off on another day within the same workweek.

Other employees can be exempted if they are salaried and perform certain white collar duties.

A "salaried" employee is not automatically "exempt" from the minimum wage and overtime requirements.

To be exempt from minimum wage and overtime requirements, an employee must be salaried, and earn at least $455 per week, and fall into one of the following categories:

- Executive exemption: The employee's primary duty consists of management of an enterprise, department or subdivision thereof; and he/she customarily and regularly directs the work of two or more employees; and has the authority to hire or fire other employees or his/her suggestions and recommendations as to the hiring, firing, advancement, promotion or any other change of status of other employees are given particular weight.
- Learned professional exemption: The employee's primary duty consists of performance of work requiring knowledge of an advanced type in a field of science or learning, customarily acquired by a prolonged course of specialized instruction. Doctor Assistants and RN's typically fall within this exemption. LPNs are not exempt unless they fall into one of the other categories.
- Administrative exemption: The employee's primary duty is the performance of office or non-manual work directly related to management or general business operations of the employer or the employer's customers; and the employee's primary duty includes work that requires the exercise of discretion and independent judgment with respect to matters of significance.
- Employees who earn more than $100,000/year may be exempt under a streamlined test that does not require that those employees pass the "duties" test.

An employer must keep records of the following information for all employees:

- Name and home address, birthdate for employees under 19, sex and occupation, hour and day of the week that workweek starts, deductions or additions to wages, total wages paid, date of payment or pay period.

An employer must keep records of the following information for all non-exempt employees:

- Regular hourly rate for overtime, daily or weekly straight time earning, overtime pay.

R. Michael Barry is a partner and Amie Willis is an associate with Epstein Becker Green, P.C. Epstein Becker & Green, P.C. is a national law firm with global reach that takes a "boutique approach" to five complementary areas of practice. Our focus is on the core practice areas of Business Law, Health Care and Life Sciences, Labor and Employment, Litigation and Real Estate.

[1]There is an alternative calculation available for hospitals and residential care establishments.

Georgia Retina Welcomes Our Newest Associate, Dr. John J. Miller

John J. Miller, M.D.

Dr. Miller, a board-certified ophthalmologist, is a native of Georgia. After graduating from the University of Georgia distinguished as First Honor Graduate, he attended the Medical College of Georgia on a full, merit-based scholarship. He completed his ophthalmology residency and vitreoretinal surgery fellowship at the University of Miami / Bascom Palmer Eye Institute, repeatedly ranked as the finest ophthalmology training program in the country by both Ophthalmology Times and U.S. News and World Report. For the duration of his final fellowship year, he served as Chief Resident. He has been an active participant in a number of clinical studies and has published articles in distinguished medical journals. He is a fellow of the American Academy of Ophthalmology and a member of the American Society of Retina Specialists. Dr. Miller is currently seeing patients at our Northside, Riverdale and Douglasville offices.

Consultations Revisited

By Donna M. McCune, COE, CCS-P

Just when you thought you understood consultations, the Centers for Medicare and Medicaid Services (CMS) published Transmittal 788 and rocked the boat. The Transmittal updates the Medicare Claims Processing Manual (MCPM), Chapter 12, §30.6.10 – Consultation Services (Codes 99241-99255) including subtle changes to the definition of consultation and stricter standards for documentation. The last time that CMS modified their policies on consultations in 1999, the criteria were relaxed leading to a surge in utilization as well as increased reimbursement. So, we will revisit this topic again to appreciate CMS' tougher stance.

The essentials remain in effect. You may file a claim for a consultation if the following criteria are met.

The consultation was requested by a physician or other qualified professional.
There is documentation of the request and need for the consultation.
A history and exam are performed with or without additional tests.
A written report is provided to the requesting physician.
No transfer of care occurs.
The consulting physician may treat patient's condition immediately or subsequently.

Definition

What is a consult? The updated definition is more detailed than before, and states,

"The intent of a consultation service is that a physician or qualified NPP or other appropriate source is asking another physician or qualified NPP for advice, opinion, a recommendation, suggestion, direction, or counsel, etc. in evaluating or treating a patient because that individual has expertise in a specific medical area beyond the requesting professional's knowledge."

So, the singular defining characteristic of a consultation is the dialogue between the requestor and the consulting physician in which the expertise of the consultant is employed to answer the question(s) posed by the attending physician. Furthermore, the attending physician intends to remain involved in the patient's care.

This emphasizes the need to document the intent of the attending physician in the chief complaint and then reiterate in your written report "who" sent the patient, "what" they sent them for, and "why". For example, documentation in the chief complaint says, "Sent by Dr. General Ophthalmologist for evaluation of the retina, due to blunt trauma." The first paragraph of the report may include "Thank you for referring Mr. Jones for an evaluation of his retina after trauma from a golf ball hit to the eye." This language establishes that the nature of the visit is consultative.

Documentation of Request

Prior to CMS' transmittal, the consultant could presume to know the intent of the attending physician and use the "who, what, and why" approach in the opening paragraph of the written report to establish that the service was a consultation. CMS states in the revised policy, *"The initial request may be a verbal interaction between the requesting physician and the consulting physician; however, the verbal conversation shall be documented in the patient's medical record, indicating a request for a consultation service was made by the requesting physician or qualified NPP."*

Consultations Revisited *continued from page 5*

A discussion with CMS officials, as reported by Part B News, revealed CMS's concern that if the two physicians do not speak, that pertinent details may be lost in translation if staff members handle the request.
Officially, staff members cannot pass along the request for consultation although extenuating circumstances might occasionally permit some latitude. Infrequently, the two physicians might speak about a patient's condition, but in ophthalmology, we believe this is not very common.

To compound the issue further, the Consultation Request section of the guidelines now states, *"A written request for a consultation from an appropriate source and the need for a consultation must be documented in the patient's medical record."* Prior to this transmittal, the request could be oral, but CMS inserted the word *written* in this section and raised the bar. How do we satisfy this requirement?

Written documentation of the request and need is easy with a shared medical record (*i.e.*, group practice, nursing facility, hospital). The request for consult is indicated in the referring physician's plan or in a separate "order". The consultant does not have to look too far to find it.

The difficulty arises when the medical record is not shared. How can the consultant know what the referring physician wrote in his plan? To cope with this issue, we suggest using a request for consultation form. A copy of the form in both providers' records confirms the consultation request and medical necessity.

Transfer of Care

Prior to 1999, any treatment rendered by the consultant was indicative of a transfer of care and disqualified the consultation. Then in 1999, the definition was liberalized to allow the consultant to treat the patient as long as he did not take over complete care of the patient (*i.e.*, all care from head to toe). The new definition is more narrowly constructed and states,

"A transfer of occurs when a physician or qualified NPP requests that another physician or qualified NPP take over the responsibility for managing the patient's complete care for the condition and does not expect to continue treating or caring for the patient for that condition. When this transfer is arranged, the requesting physician or qualified NPP is not asking for an opinion or advice to personally treat this patient and is not expecting to continue treating the patient for the condition."

Let's consider how to apply this rule to cataract. If the requesting physician states "refer to Dr. Surgeon for cataract surgery" and does not plan to be involved in any care related to the cataract, then the surgeon should not report the visit as a consultation. Alternately, if the requesting physician states "consultation requested to evaluate cataract and determine whether cataract surgery is appropriate. I look forward to receiving your advice and will resume care thereafter." then the surgeon may report the visit as a consultation. So, even if the surgeon decides to perform cataract surgery, if the patient will be sent back to the requesting physician for follow-up care related to the condition then a consultation applies. For example, the requesting physician expects to follow the patient after the consultation for conditions related to cataract such as ametropia, posterior capsule opacity, dislocation of the pseudophakos, anisometropia, and cataract in the fellow eye. These conditions link to the condition of cataract.

OIG Report

Whether coincidence or not, the Office of Inspector General (OIG) published a report (OEI-09-02-00030) on March 29, 2006 citing, *"in 2001…Medicare allowed approximately $191 million more than should have been allowed for services that were billed as consultations, but did not meet Medicare's definition of a consultation."* The OIG recommends that carriers educate providers on consultation criteria. Does this foreshadow increased carrier inquiries? We think it does.

Conclusion

From 1999 to 2005, ophthalmologists increased their use of consultations by 67%. CMS lists ophthalmology in the top seven specialties with heavy use of consultations. Payer scrutiny of consultations has already begun. The revisions cited here are merely the most salient points in the transmittal; we strongly recommend review of the entire regulation and revisiting this subject with physicians and staff ASAP.

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Donna McCune is vice president with Corcoran Consulting Group. The company provides extensive consultation in third party reimbursement issues, particularly concerning Medicare. Their clients include ophthalmologists, optometrists, opticians, clinics, hospitals, medical schools, ASCs and manufacturers. She received her certification as a Certified Coding Specialist for Physicians from the American Health Information Management Association in the fall of 1998 and Certified Ophthalmic Executive Certification in the spring of 1999.A nationally recognized speaker, Donna participates annually at the American Academy of Ophthalmology (AAO) Meeting and the Annual Congress of the American Society of Ophthalmic Administrators (ASOA), as well as several state ophthalmic and optometric society meetings. She also provides private consulting to vision care providers.

What's Your Diagnosis? *continued from page 1*

Workup

She was referred to a neurologist the day of presentation for hospitalization and emergent evaluation. A complete neurologic exam was unremarkable. Lumbar puncture yielded thin, clear cerebrospinal fluid with a normal opening pressure of 150 mmHg. Chemical, cytologic, and microbiologic evaluations of the cerebrospinal fluid were all normal. MRV revealed normal dural sinuses. MRI of the brain revealed multifocal white matter changes diffusely scattered throughout the cerebral cortex, cerebellum, and midbrain. (**Figure 3**)

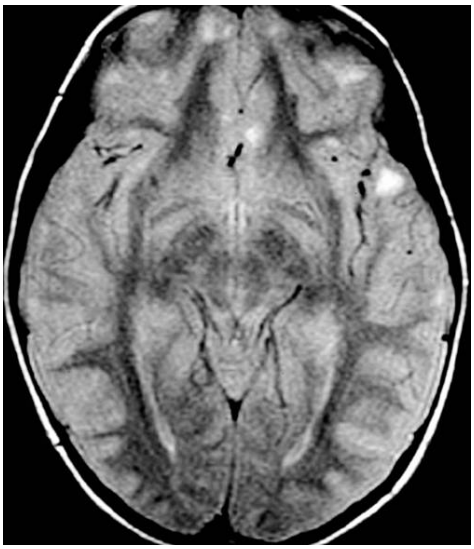

Figure 3

Hospital course

Her blood pressure was checked at various times during the course of her hospitalization. The first several checks were normal. About 10 hours after admission, she developed diaphoresis. A check of vital signs during the symptoms revealed tachycardia with heart rate of 180 beats per minute. Blood pressure was 240/160.

She was transferred to the intensive care unit, where continuous monitoring of vital signs revealed labile blood pressure and episodic tachycardia. Additional laboratory studies included the following catecholamine tests: random total urine metanephrines = 22,295 (normal 200-750), random urine norepinephrine = 4681 (normal 20-100), 24 hour urine vanyllilmandelic acid = 15.1 (normal < 2.3). A renal ultrasound showed a 3.5 x 3.5 x 3 cm right adrenal mass. CT of the abdomen also showed the right adrenal mass.

The right adrenal mass was surgically resected. Histopathologic analysis confirmed the tumor to be a pheochromocytoma.

Discussion

Pheochromocytoma is a tumor of neural crest origin that is characterized by the episodic release of catecholamines. Epidemiologically, it has a prevalence of approximately 2 cases per million people. Middle aged adults are most commonly affected. The tumors are most commonly unilateral and solitary, located in the adrenal glands or paraspinal sympathetic ganglia.

The clinical presentation of pheochromocytoma is varied. Patients often complain of episodic diaphoresis, headaches, and palpitations. As such, people with this condition are often initially diagnosed with panic attacks or seizure disorder. Sustained or episodic hypertension is common, as well. Severe episodes of catecholamine release may lead to lactic acidosis or rhabdomyolysis. The presentation in this case consisted of unrecognized episodic hypertension leading to neuroretinopathy and encephalopathy.

The diagnosis is confirmed by measuring abnormal urine or plasma catecholamines, followed by CT or MRI for anatomic localization. Prognosis following resection of benign tumors is quite good, with a five year survival of 95%.

As with most neoplasms, pheochromocytomas do not strictly adhere to the clinical and epidemiologic generalizations outlined above. As a reminder of the varied ways in which this tumor behaves, oncologists use the "rule of 10s." Of all pheochromocytomas, they are approximately 10% malignant, 10% bilateral, 10% extra-adrenal, 10% pediatric, and 10% familial. The familial cases are important to recognize, as these cases are associated with syndromes with additional clinicopathologic manifestations. Specifically, pheochromocytomas may be seen in neurofibromatosis, Von-Hippel Lindau syndrome, and multiple endocrine neoplasia (MEN) types 2a and 2b.

In this young patient, the paroxysmal tachycardia and hypertension resolved following removal of the tumor, and catecholamine metabolite levels normalized. Six months later, her vision had improved to 20/30 in both eyes. The disc edema had resolved, and the lipid exudates within the macula had improved. With complete resolution of the exudation, her vision may fully recover. *-JJM*

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Our Physicians

Michael S. Jacobson, M.D. Scott Lampert, M.D.
Mark J. Rivellese, M.D. Jay B. Stallman, M.D.
Sean S. Koh, M.D. Atul Sharma, M.D.
Robert A. Stoltz, M.D., Ph.D.
John J. Miller, M.D.

GEORGIA RETINA

465 Winn Way Ste 100
Decatur, GA 30030
(404) 299-5209

114 Cherry St Ste F
Marietta, GA 30060
(770) 218-1888

5671 P'tree-Dunwoody Rd Ste 610
Atlanta, GA 30342
(404) 255-9096

155 Medical Way Ste E
Riverdale, GA 30274
(770) 907-9400

575 Professional Dr Ste 330
Lawrenceville, GA 30045
(678) 405-0922

6095 Professional Pkwy Ste B202
Douglasville, GA 30134
(678) 303-0136

toll free 888-GA-Retina

www.garetina.com