

**IN THIS ISSUE**

Halting Alzheimer's	2
Gains Against GERD	2
UHealth Clinical Trials	3
Frontline Joint Care	4
Lowering Lipids	4

NEWS FOR PHYSICIANS AND HEALTHCARE PROFESSIONALS FROM UNIVERSITY OF MIAMI HEALTH SYSTEM

Sylvester Comprehensive Cancer Center/Neurosurgery

## Glimmer of Hope

Fluorescent technology helps improve accuracy of intricate neurosurgery

**N**early 70,000 people will be diagnosed with primary brain tumors this year. A new intraoperative visualization technology that makes a brain tumor glow could help extend their lives.

Ricardo Komotar, M.D. (right), assistant professor of neurological surgery at the Miller School of Medicine and co-director of surgical neuro-oncology at Sylvester Comprehensive Cancer Center, recently used the technique at University of Miami Hospital.


Palm Beach County Sheriff's Deputy Shawn Monti, the father of five, sought out Komotar after he was diagnosed with an

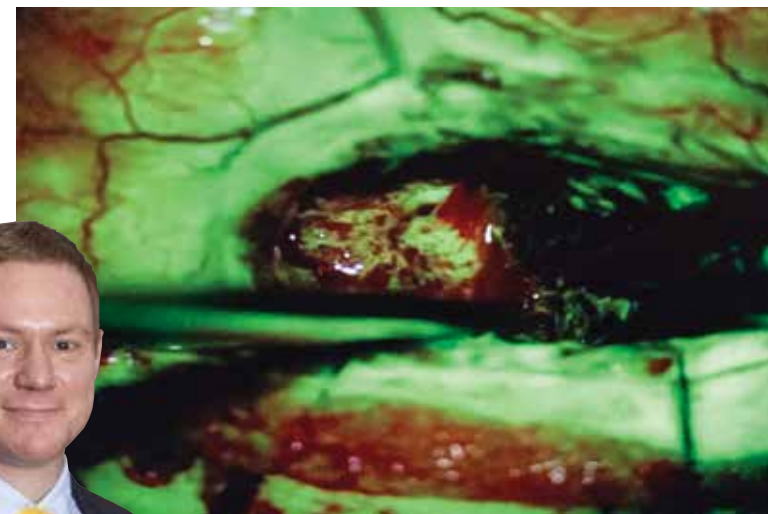
aggressive glioblastoma in fall 2013 and given just six months to live. After Komotar performed a successful first surgery,

Monti's cancer recurred in a different location—adjacent to the motor strip that controls the body's movements.

During the second surgery, Komotar injected Monti with sodium fluorescein, a fluorescent tracer that is leaked by tumor cells, making them glow and appear distinct from healthy tissue when viewed through a special filter. Monti was kept awake during the procedure to make sure his mobility was not being affected.

Now more than a year out from his initial diagnosis, Monti is back at work and treasuring every additional day of life his state-of-the-art care has made possible.

Surgery alone is not a cure for glioblastoma; patients typically also require chemotherapy and radiation. But, says Komotar, biofluorescence is "a potential game changer. It will, hopefully, become the standard of care for difficult cases." 



Tumor cells glow with a distinctive green hue when injected with sodium fluorescein, facilitating surgical resection.



Alain Alminana

**"Using biofluorescence maximizes our ability to safely remove the tumor while preserving healthy tissue."**

— Ricardo Komotar, M.D.,

Co-Director of Surgical Neuro-Oncology, Sylvester Comprehensive Cancer Institute

### Phase II Clinical Trial: Heat Shock Protein for Brain Cancer

This Sylvester Comprehensive Cancer Center clinical trial is open to qualified brain cancer patients with glioblastoma multiforme. The trial targets the immune system and activates a patient specific T-cell response using heat shock protein vaccine HSPPC-96. Sylvester is the only cancer center in Florida to offer this treatment. Details on this and other Sylvester trials at [sylvester.org/clinical-trials](http://sylvester.org/clinical-trials). To refer a patient or for more information, contact Ricardo Komotar, M.D., at [rkomotar@med.miami.edu](mailto:rkomotar@med.miami.edu).

## DIABETES INSIGHTS


### Prevention Strategies Show Long-Term Benefits

**AN ESTIMATED 79 MILLION**

American adults are currently at high risk for developing type 2 diabetes. An NIH-funded study indicates that long-term risk can be reduced through lifestyle or medical strategies.

Ronald Goldberg, M.D. (below), professor of medicine at the Miller School's Diabetes Research Institute, served as the University's principal investigator for the Diabetes Prevention Program Outcomes Study, which evaluated the effects of two diabetes interventions—lifestyle modification and the diabetes medicine metformin—15 years after the initial NIH Diabetes Prevention Program (DPP) study.

Following the initial randomized treatment phase, all DPP participants were offered lifestyle intervention. Type 2 diabetes development was significantly reduced among participants who had received either of the original interventions.

"People with type 2 diabetes are at much higher risk for heart disease and stroke than those who do not have diabetes," Goldberg says. "So a delay in risk factor development or improvement in risk factors may prove to be beneficial." 

**▶ To refer a patient for a metabolic syndrome, diabetes, or cardiovascular consult, please call 305-243-3636.**

### Wake-Up Call On Apnea Risks


**SLEEP-DISORDERED BREATHING**

(SDB) such as obstructive sleep apnea raises Hispanic-Americans' risk for diabetes and hypertension, according to a landmark study

coauthored by Alberto R. Ramos, M.D., M.S.P.H., assistant professor of clinical neurology and co-director of the University of Miami Sleep Medicine Program.

The study examined the prevalence of sleep apnea and its relation to high blood pressure and diabetes among 14,440 middle-aged Hispanics from across the U.S.

Though 33 percent of men and 19 percent of women in the study had sleep apnea, only 1.3 percent had been previously diagnosed with the condition.

Even after adjusting for body mass index and waist circumference, the study found significant associations between sleep apnea, diabetes, and hypertension, suggesting a large burden of disease may be due to untreated SDB. 

**▶ To refer a patient or to consult with a UHealth sleep medicine specialist, please call 305-482-5113 or email [uhealthsleep@med.miami.edu](mailto:uhealthsleep@med.miami.edu).**

## FAST STATS

**NIH 15-Year Follow-Up: Reductions in Diabetes Risk**

- 27%** Lifestyle intervention
- 17%** Metformin
- 28%** Fewer microvascular complications

(in patients who avoided diabetes through either intervention)

**Hispanic Adults with Apnea: Elevated Disease Risks**

- 90%** Higher chance of diabetes
- 44%** Higher chance of hypertension
- 50%** Higher chance of impaired glucose tolerance



Kate Riccio

## Halting Alzheimer's

An estimated five million people in the U.S. suffer from mild-to-moderate Alzheimer's disease, and their numbers are growing at an alarming rate. The recently launched NOBLE study is evaluating an investigational neuroprotective drug, T-817MA, which may have the potential to modify the pace of the disease.

"Alzheimer's medications currently in use were approved more than ten years ago, and are symptomatic therapies that do not address the underlying disease process that kills neurons," says Clinton Wright, M.D., M.S., scientific director of the Evelyn F. McKnight Brain Institute and principal investigator of the UM arm of the NOBLE study. "We are desperately in search of a drug that can slow the disease or stop in its tracks, so this study is generating some excitement."

The University of Miami Memory Disorders Center is a collaborative multidisciplinary program spearheaded by the departments of neurology and of psychiatry and behavioral sciences. This resource offers access to the very latest therapeutic options, and the UM team sees patients at sites around South Florida. "We provide a comprehensive evaluation to disentangle the underlying cause of dementia," Wright notes.

▶ For more information about Memory Disorders Center diagnostic evaluation services and clinical studies, call 305-243-6633 or 305-355-0965.

### NOBLE STUDY: FAST FACTS

▶ **PHASE 2** multicenter, randomized, double-blind, placebo-controlled, parallel group study

▶ **CONDUCTED BY** the Alzheimer's Disease Cooperative Study; sponsored by Toyama Chemical Co., Ltd.

▶ **PROSPECTIVE PARTICIPANTS**

- between ages 55-85
- mini-mental score between 12-22
- on stable dose of Aricept®, Namenda®, or Exelon® for three months
- accompanied by a study partner or family caregiver

▶ For more information, visit [NOBLEstudy.org](http://NOBLEstudy.org) or contact the Miller School of Medicine Memory Disorders Center at 305-243-0184.



### Gastroenterology

## Gains Against GERD

Gastroesophageal reflux disease (GERD), the most common digestive disorder, affects about 20 percent of the general population. Left untreated, it can lead to serious complications such as esophagitis, stricture, Barrett's esophagus, and elevated risk for esophageal adenocarcinoma.

Side effects of proton pump inhibitors (PPIs), the most commonly prescribed class of drugs for GERD, range from headaches, nausea, abdominal pain, and digestive discomfort to hair loss, osteoporosis, and increased risk for pneumonia. Nissen fundoplication, a surgical intervention for patients who do not tolerate PPIs well or do not want to take them on a long-term basis, brings risks associated with surgery, and its effectiveness may wane over time.

Newer, less invasive, FDA-approved GERD treatment options are now being offered by the gastroenterology team at UHealth. These interventions, LINX® and Stretta®, offer a middle path between medication and surgery for GERD patients.

"The manufacturers of these modalities insist that clinicians have specialized training," says Baharak Moshiree, M.D., an associate professor of medicine and director of motility at UHealth Gastroenterology (above, in UM's motility lab). "Only a university setting such as UHealth can offer all GERD treatment options, allowing us to precisely meet the patient's needs."

▶ To refer a patient for motility testing, use UHealth CareLink (see below) or call 305-243-8644. For more information on UHealth gastroenterology services, visit [medicine.miami.edu/gastroenterology](http://medicine.miami.edu/gastroenterology).



### REFERRAL CARE AT YOUR FINGERTIPS

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- Free, web-based, secure patient Epic® EMR viewing platform
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- Seamless, real-time reporting of patient results

FOR INFORMATION ABOUT REGISTERING FOR CARELINK, CONTACT KELLY HEDGES-PEERMAN AT [KHEDGES@MED.MIAMI.EDU](mailto:KHEDGES@MED.MIAMI.EDU).

UHealth's Division of Gastroenterology is the only team in Florida to offer a complete array of treatments for GERD, including the latest minimally invasive procedures.

### DIRECT LAB ACCESS

**ESOPHAGEAL MOTILITY** must be considered when selecting GERD interventions. The University of Miami's dedicated Endoscopy and Motility Laboratory performs evaluation of esophageal motility. Because it is an open lab, referring physicians can order the test directly and receive results within a week.

### LINX® Reflux Management System

This sterile, single-use device is surgically placed at the lower esophageal sphincter (LES). Composed of a ring of magnetized titanium beads, LINX expands in response to swallowing, then contracts to close the LES. Study results indicate that the benefits of LINX outweigh risks to patients with persistent GERD.

### Stretta® Procedure

Performed endoscopically under conscious sedation, this 60-minute procedure delivers radiofrequency energy to the LES, improving mass and tone. More than 30 peer-reviewed studies have documented Stretta's safety and long-term efficacy in improving GERD patients' quality of life and reducing the need for medication.

## CLINICAL TRIALS

### BENIGN PROSTATIC HYPERPLASIA (BPH):

The Miller School of Medicine is participating in a multicenter international trial of Prostate Artery Embolization (PAE), a minimally invasive treatment for BPH. In PAE, tiny particles are injected into prostate arteries, reducing blood flow, prostate size, and symptoms of BPH. UHealth is the only South Florida site offering PAE in the study, which evaluates results of PAE vs. TURP (transurethral resection of prostate). For details, call 305-243-3404 or 305-243-4917 or contact UM P.I. Shivank Bhatia, M.D., at [sbhatia1@med.miami.edu](mailto:sbhatia1@med.miami.edu).



Shivank Bhatia, M.D.

### AGE-RELATED MACULAR DEGENERATION (AMD):

Retinal specialist Philip J. Rosenfeld, M.D., Ph.D., a professor of ophthalmology at Bascom Palmer Eye Institute and pioneer of groundbreaking interventions for "wet" AMD, is now conducting clinical trials to determine if Lampalizumab® can slow the progression of the more common "dry" form of AMD, for which there are no proven therapies. Eligible patients may enroll at Bascom Palmer's Miami and Palm Beach Gardens locations. Rosenfeld is also conducting a stem cell trial for AMD. For details about these and other Bascom Palmer clinical trials, visit [bascompalmer.org/research/clinical-trials](http://bascompalmer.org/research/clinical-trials).



Philip J. Rosenfeld, M.D., Ph.D.

### HIV/AIDS:

Miller School professors Margaret A. Fischl, M.D. and Gwendolyn B. Scott, M.D., have received a \$5.67 million grant from the NIH-NIAID for their ongoing work in HIV/AIDS. Fischl, director of the Miami Center for AIDS Research, notes that the new research will focus on novel approaches to suppressing HIV and its complications. Also funded are studies at the Pediatric Perinatal HIV Clinical Trials Unit, co-directed by Fischl and Scott, director of the Division of Pediatric Infectious Disease and Immunology. Search for HIV studies on [uhealthsystem.com/clinical-trials](http://uhealthsystem.com/clinical-trials) or call 305-243-3838.



Gwendolyn B. Scott, M.D. and Margaret A. Fischl, M.D.

The University of Miami conducts more than 2,000 clinical trials each year, including Phase II or III investigations at Sylvester Comprehensive Cancer Center, Bascom Palmer Eye Institute, and other programs throughout the Miller School of Medicine and University of Miami Health System. The above highlights and following listing represent a brief sampling of clinical trials at the University that are currently enrolling. For details or information on other clinical trials, visit [uhealthsystem.com/clinical-trials](http://uhealthsystem.com/clinical-trials).

**A Randomized Phase II/III Study to Assess the Efficacy of Trametinib (gsk 1120212) in Patients With Recurrent or Progressive Low-Grade Serous Ovarian Cancer or Peritoneal Cancer**  
Investigator: Brian Slomovitz  
National Clinical Trials Identifier: NCT02101788  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Gynecologic Cancer

**A Randomized, Double-Blind, Phase 2 Study of Ruxolitinib or Placebo in Combination with Capecitabine in Subjects with Advanced or Metastatic HER2-Negative Breast Cancer**  
Investigator: Stephen Richman  
National Clinical Trials Identifier: NCT02120417  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Breast Cancer

**The Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) (Phase III)**  
Investigator: Jennifer Marks  
Division: Endocrinology  
Therapeutic Area: Diabetes

**Membranous Nephropathy Trial Of Rituximab (MENTOR): A Multicenter Randomized Controlled Trial of Rituximab Versus Cyclosporine in the Treatment of Idiopathic Membranous Nephropathy (Phase III)**  
Investigator: Dollie Green  
Division: Nephrology  
Therapeutic Area: Chronic Kidney Disease

**ALEX: Randomized, Multicenter, Phase III, Open-Label Study of Alectinib Versus Crizotinib in Treatment-Naïve Anaplastic Lymphoma Kinase-Positive Advanced Non-Small Cell Lung Cancer**  
Investigator: Mohammad Jahanzeb  
National Clinical Trials Identifier: NCT02075840  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Thoracic Oncology

**A Phase 3 Efficacy and Safety Study of Ataluren (PTC124®) in Patients with Nonsense Mutation Cystic Fibrosis**  
Investigator: Matthias Salathe  
National Clinical Trials Identifier: NCT02139306  
Division: Pulmonary and Critical Care  
Therapeutic Area: Lung Disease

**SWOG S0820: A Double-Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III – Preventing Adenomas of the Colon**  
Investigator: Ikechukwu Akunyili  
National Clinical Trials Identifier: NCT01349881  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Colorectal Cancer

**GSUS3340154A Phase 2b Randomized, Open-Label Study of 200 mg or 400 mg SofosbuvirRBV for 24 Weeks in Genotype 1 or 3 HCV-infected Subjects with Renal Insufficiency**  
Investigator: Paul Martin  
Division: Hepatology

**Open-Label, Randomized, Multicenter Study Comparing the Sequence of High-Dose Aldesleukin (Interleukin2) and Ipilimumab (Yervoy) in Patients with Metastatic Melanoma (Phase III)**  
Investigator: Lynn Feun  
National Clinical Trials Identifier: NCT01856023  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Melanoma and Related Skin Cancers

**A Multicenter, Double-Blind, Placebo-Controlled, Proof of Concept Study to Evaluate the Efficacy and Tolerability of BAF312 in Patients with Polymyositis (Phase II)**  
Investigator: Dana Ascherman  
Division: Rheumatology and Immunology

**A Phase II Study of Chemoradiation for Bladder Preservation in Patients with Muscle Invasive Bladder Carcinoma after Complete Response to Neoadjuvant Chemotherapy**  
Investigator: Adrian Ishkanian  
National Clinical Trials Identifier: NCT02145390  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Prostate, Bladder, and Kidney Cancers

**Phase I/II Open-Label, Multiple-Dose, Dose-Escalation Study to Evaluate the Safety and Tolerability of IMO-8400 in Patients with Relapsed or Refractory Waldenström's Macroglobulinemia**  
Investigator: James Hoffman  
National Clinical Trials Identifier: NCT02092909  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Non-Hodgkin Lymphoma

**Phase III, Randomized, Controlled Study of Cabozantinib (XL184) vs Everolimus in Subjects with Metastatic Renal Cell Carcinoma that Has Progressed after Prior VEGFR Tyrosine Kinase Inhibitor Therapy**  
Investigator: Jaime Merchan  
National Clinical Trials Identifier: NCT01865747  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Kidney Cancer

**RTOG 1203: A Randomized Phase III Study of Standard vs. IMRT Pelvic Radiation for Postoperative Treatment of Endometrial and Cervical Cancer (TIMEC)**  
Investigator: Lorraine Portelance  
National Clinical Trials Identifier: NCT01672892  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Gynecological Cancer

**A Randomized, Blinded, Placebo-Controlled, Dose-Finding Study to Assess the Safety and Efficacy of the Oral Thrombopoietin Receptor Agonist, Eltrombopag, Administered to Subjects with Acute Myelogenous Leukemia Receiving Induction Chemotherapy (Phase II)**  
Investigator: Ronan Swords  
National Clinical Trials Identifier: NCT01890746  
Division: Sylvester Comprehensive Cancer Center  
Therapeutic Area: Leukemia, Lymphoma, and Myeloma

**STEADY-PD III (Safety, Tolerability, and Efficacy Assessment of Isradipine for PD) (Phase III)**  
Investigator: Corneliu Luca  
National Clinical Trials Identifier: NCT02168842  
Division: Neurology  
Therapeutic Area: Parkinson's Disease


## Orthopaedics

# Frontline Joint Care

**T**he demand for total joint replacement is rising dramatically, driven by factors including the growing prevalence of obesity and heavy demands placed by active baby boomers on their joints.

The fellowship-trained faculty of the Miller School's multidisciplinary Department of Orthopaedics provide critical mass in joint replacement capabilities. Joint surgeons Raymond P. Robinson, M.D., FACS, Michaela M. Schneiderbauer, M.D., Ph.D., M.B.A., and Fernando E. Vilella-Hernandez, M.D., have recently been joined by Victor H. Hernandez, M.D., M.S.

Schneiderbauer and Hernandez have subspecialty training and extensive experience in anterior hip replacement, which is performed through a small incision on the front (anterior), rather than the side or back, of the joint.

UHealth is one of the few facilities in South Florida to offer the muscle-sparing anterior technique for hip replacement. The team also provides bilateral knee and hip replacement and partial knee (including patellofemoral and uni-condylar) replacements. 

► **The UHealth Orthopaedics joint replacement team performs surgeries at University of Miami Hospital (UMH) and offers consultations at UMH and in Boca Raton, Hialeah, and Kendall. For more information or to refer a patient, call 305-243-3000.**

### Anterior Technique Yields Benefits

- Recovery often accelerated because muscles are spared
- Fewer restrictions during recovery
- Faster return to activities of daily living



(From left) UHealth orthopaedic surgeons Fernando E. Vilella-Hernandez, Michaela M. Schneiderbauer, Raymond P. Robinson, and Victor H. Hernandez

**UHealth offers unsurpassed expertise in all minimally invasive joint replacement techniques, including the anterior approach to hip replacement.**



### UHealth At Your Fingertips

With the free UHealth mobile app, you can find a UHealth doctor, request appointments, obtain maps and parking information, and much more. **Download it today!**

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## Cardiology

# Lowering Lipids

**A**mid the millions of people at risk for serious disease due to elevated cholesterol and triglycerides, those with abnormally high lipid scores present a significant clinical challenge.

"Their levels may be high due to genetic factors, because they can't tolerate medication, or because they are unable to follow lifestyle regimens," says Carl E. Orringer, M.D., an associate professor of medicine who is an expert in lipid management and president-elect of the National Lipid Association. "We are here to partner with community-based practitioners in the prevention of cardiovascular disease in patients with difficult lipid disorders."

After an in-depth evaluation of a patient's clinical presentation and cardiovascular risk factors, recommended interventions may include new combinations of medications. An LDL apheresis program, which can lower cholesterol up to 75 percent in biweekly treatments, is slated to launch later this year. 

► **To refer a patient to UHealth's preventive cardiovascular program, call 305-243-5554.**



## UHEALTH CONTINUING MEDICAL EDUCATION

**March 13-14, 2015**  
**Hepatobiliary Disease in Clinical Practice: Update XXI**  
[cme.med.miami.edu](http://cme.med.miami.edu)  
InterContinental Hotel, Miami, FL  
12.50 AMA PRA Category 1 Credits™

**March 14-15, 2015**  
**Holistic Holiday at Sea: A Voyage to Well Being**  
[cim.med.miami.edu/education/](http://cim.med.miami.edu/education/)  
Departs from and returns to Miami, FL; visits Jamaica, Cayman Islands, Bahamas, and Mexico  
32.35 AMA PRA Category 1 Credits™, 45 CEU Credits

**March 28-29, 2015**  
**Art & Science of Acupuncture for Physicians: Auricular Acupuncture Module**  
[icamp.med.miami.edu](http://icamp.med.miami.edu)  
Highland Professional Building  
University of Miami Miller School of Medicine, Miami, FL  
14.00 AMA PRA Category 1 Credits™

**April 10-11, 2015**  
**Nutrition MATTERS: Add Integrative Clinical Nutrition to Your Practice**  
[cim.med.miami.edu/education/clinical-nutrition](http://cim.med.miami.edu/education/clinical-nutrition)  
Miami Marriott Biscayne Bay, Miami, FL  
14.00 AMA PRA Category 1 Credits™, 14 CEU Credits

**April 15, 2015**  
**Advances in Minimally Invasive Cranial Neurosurgery**  
[cme.med.miami.edu](http://cme.med.miami.edu)  
Morton's Steakhouse, Fort Lauderdale, FL  
1.00 AMA PRA Category 1 Credits™

**April 17, 2015**  
**2015 Florida Ethics: Debates, Decisions, Solutions**  
[fhn.med.miami.edu/conferences](http://fhn.med.miami.edu/conferences)  
Miami Marriott Biscayne Bay, Miami, FL  
6 AMA PRA Category 1 Credits™

**May 13-14, 2015**  
**Urologic Oncology and Robotic Surgery**  
[cme.med.miami.edu](http://cme.med.miami.edu)  
Eden Roc Hotel, Miami Beach, FL  
7.5 AMA PRA Category 1 Credits™



Synergy Miami 2014

**June 19, 2015**  
**Bascom Palmer Eye Institute's 51st Annual Residents' Days**  
[bascompalmer.org/cme](http://bascompalmer.org/cme)  
Bascom Palmer Eye Institute, Miami, FL  
Credit TBD

**September 10, 2015**  
**Update on Cerebrovascular Neurosurgery: Repairing Brain Aneurysms and AVMs**  
[cme.med.miami.edu](http://cme.med.miami.edu)  
Morton's Steakhouse, West Palm Beach, FL  
1.00 AMA PRA Category Credits™

**October 29-31, 2015**  
**Miami Valves 2015**  
[miamivalves.org](http://miamivalves.org)  
The Alexander Hotel, Miami Beach, FL  
Credit TBD

Online CME courses are also available and include **Medical Errors Prevention, Domestic Violence, and HIV/AIDS Update**. Visit [cme.med.miami.edu](http://cme.med.miami.edu) for more information.

**CME Contact Info** Continuing Medical Education: 305-243-6716 / Bascom Palmer Eye Institute: 305-326-6110