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ADVANCES IN NEUROLOGY AND NEUROSURGERY

Weill Cornell Medicine

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SAVE THE DATE

Brain Attack and Cerebrovascular Disease – Update 2017
May 12, 2017 | 7:45 am to 5 pm
New York Academy of Medicine
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BEST HOSPITALS U.S.News & World Report NATIONAL NEUROLOGY & NEUROSURGERY 2016-17

NewYork-Presbyterian Neurology and Neurosurgery ranks #3 in the nation.

Making Strides in the Treatment of Hemorrhagic Stroke

In June 2016, NewYork-Presbyterian Hospital was certified by The Joint Commission and the American Heart Association/American Stroke Association as a Comprehensive Stroke Center, the highest level of stroke certification a hospital can receive. The recognition is well-deserved, shining a light on the long-term experience and highly specialized expertise of NewYork-Presbyterian's stroke teams and the availability of dedicated neurointensive care units, 24/7 neurosurgical and endovascular care, advanced imaging, and treatment capabilities for patients with ischemic and hemorrhagic stroke. NewYork-Presbyterian physicians continue to be at the forefront of treatment and technology used in the care of patients with hemorrhagic stroke caused by bleeding aneurysms and arteriovenous malformations (AVMs), with outcomes among the best in the country.

The physicians who comprise NewYork-Presbyterian's stroke teams agree that collaborations among neurosurgeons, neurologists, neurointerventionalists, neurointensivists, and neuroradiologists are a key factor in the successful outcomes achieved in their patients with stroke. "NewYork-Presbyterian has a large group of physicians specializing in stroke who see each other every day, consult with each other, and share information, all of which is extremely beneficial to our patients," says **Robert A. Solomon, MD,** a pioneer in the treatment of cerebral aneurysms, who this year will mark his 20th anniversary as Neurosurgeon-in-Chief at NewYork-Presbyterian/Columbia University Medical Center. "Whether it's intensive care or endovascular treatment, stereotactic radiosurgery or open micro-neurosurgery, we can provide the highest quality stroke care."

"Close, collaborative working relationships among the Hospital's neurosurgeons, neurologists, and neuro-related specialists are the norm at each of the Hospital's campuses – not only for stroke, but also for all neurological disorders and injuries," emphasizes **Matthew E. Fink, MD,** Neurologist-in-Chief, NewYork-Presbyterian/Weill Cornell Medical Center. "We trust each other and we are willing to listen and defer to each other. This results in a quality of care that is virtually without peer."

"It is important to distinguish between an ischemic stroke that turns hemorrhagic versus a hemorrhage or a hematoma in the brain," says **Randolph S. Marshall, MD, MS,** Chief of the Stroke Division, NewYork-Presbyterian/Columbia. "They have overlapping pathophysiology, but the management can be different depending on the type of hemorrhagic stroke. The common thread is hypertension. However, the key for hemorrhagic stroke is to find out if there is some other cause. In younger people, or those without a history of hypertension, you have to do additional testing to find out what might be the cause of bleeding, and in particular, to rule out an underlying arteriovenous malformation."

New Directions in Surgical and Endovascular Techniques

NewYork-Presbyterian neurosurgeons, endovascular surgeons, and neurologists led by internationally renowned leaders in these fields, are pursuing the development and evaluation of new techniques, devices, and technology to treat complex hemorrhagic stroke. "Developments in surgical and endovascular approaches are providing great potential for improving recovery of patients with hemorrhagic stroke," says **Philip E. Stieg, PhD, MD,** Neurosurgeon-in-Chief at NewYork-Presbyterian/Weill Cornell, who edited the definitive textbook on AVMs, *Intracranial Arteriovenous Malformations.*

(continued on page 2)

Making Strides in the Treatment of Hemorrhagic Stroke *(continued from page 1)*

"Advances in surgical treatment involve more minimally invasive approaches with less retraction on the brain so that we can prevent any secondary injuries," says Dr. Stieg. "New clip configurations – smaller clips and mini clips – increase the diversity of aneurysm types that we can clip. For patients who develop severe brain swelling and herniation after removal of a clot, we can perform a hemicraniectomy to allow the swelling to move outward rather than inward. This buys us time. The portion of the skull that is removed is reconstructed with a plastic prosthesis using advanced 3D remodeling techniques based on an individual's CT scan. Once the brain swelling is reduced, we replace the removed section."

NewYork-Presbyterian's multidisciplinary stroke teams encompass expertise in surgical, endovascular, and radiosurgical techniques for the treatment of AVMs. "Together we craft a personalized approach and develop the best plan for repair for each patient – one that offers the lowest risk and the highest benefit we can achieve," says **E. Sander Connolly, Jr., MD,** Surgical Director of the Neurointensive Care Unit at NewYork-Presbyterian/Columbia. "A patient may require a bypass, a stent, coiling, or clipping, but what's really important to know is that whatever treatment is decided, it will be performed by a super subspecialist."

Dr. Connolly is quick to note, however, that team members are very conservative in their approach to minimally symptomatic lesions – whether related to an unruptured aneurysm or unruptured AVM. "Sometimes patients feel that when they are referred to a large academic medical center for care, they will automatically hear, 'You need an operation.' However, that couldn't be further from the truth. I would say that 10 percent or less of the patients referred to us for these minimally symptomatic lesions will be recommended for an invasive therapy. Most patients will only need to be followed."

Ruptured aneurysms are increasingly being treated endovascularly with either coils or stents. Endovascular surgeons at Columbia University Medical Center and Weill Cornell Medicine are lead investigators in trials of a new stent and delivery system that may provide a mechanism to treat wide-necked intracranial aneurysms with coils and reduce the chance of rupture. The LVIS HUD is a stent mesh tube placed across the neck of the aneurysm and intended to remodel the blood vessel and provide support for the coils placed inside the aneurysm. The purpose is to close off the aneurysm neck and lower the chance of rupture.

Our neurosurgeons and neurologists are also participating in the international MISTIE III trial, which is focused on intracerebral hemorrhage for which there is currently no effective treatment. MISTIE is a series of clinical trials evaluating approaches to quickly remove an intracerebral hemorrhage from the brain. The MISTIE III trial is investigating the treatment of intracerebral hemorrhage with minimally invasive surgery and intermittent dosing of the clot-busting drug alterplase, a recombinant tissue plasminogen activator (rtPA). The study premise is that by removing the blood clot faster, injury to the brain will be reduced and the patient's long-term prognosis will improve.

"This trial is evaluating a minimally invasive surgical technique involving stereotactic placement of a catheter – instilled with the thrombolytic drug – directly into an intracerebral hemorrhage to aspirate the congealed blood clot," says **Dana Leifer, MD,** Director of the Stroke and Neuroscience Step-Down Unit at NewYork-Presbyterian/Weill Cornell. "This may seem somewhat paradoxical because tPA is a drug that dissolves blood clots. But when administered after the bleeding has stopped and when the hemorrhage is very thick and has a jelly-like consistency, the tPA dissolves the clot so that the blood drains out through the catheter. The catheter is kept in place for a period of up to three days. Preliminary studies have shown that we can considerably decrease the volume of the hemorrhage with this technique and that it appears to have some potential benefit in terms of outcome."

Dr. Jared Knopman and Dr. Halinder S. Mangat

NewYork-Presbyterian's interventional neuroradiologists and endovascular neurosurgeons also have extensive experience with flow-diverting stents to treat unruptured large and giant aneurysms at the skull base. "We are always among the first to obtain the newest technology that comes into the constantly evolving field of endovascular neurosurgery," says **Jared Knopman, MD**, a neurosurgeon and interventional neuroradiologist at NewYork-Presbyterian/Weill Cornell. "New devices and new techniques are continually being developed, making the field safer and allowing us to do procedures that we had no capacity to do years ago."

Until these devices became available, suitable treatment for these anatomically challenging conditions did not exist. More recently, technological advances and clinical trial results suggest that flow diverters now can be safely and effectively used in treating ruptured aneurysms, posterior circulation aneurysms, and distal anterior circulation aneurysms that are difficult to treat with conventional clipping or coiling.

Philip M. Meyers, MD, and **Sean D. Lavine, MD,** serve as Clinical Co-Directors of Neuroendovascular Services at NewYork-Presbyterian/Columbia. Dr. Meyers points to institutional experience as key to successful outcomes. "Good outcomes are associated with a large volume of cases, low treatment risk, and highly specialized cerebrovascular experts with a sole focus on the treatment of cerebral aneurysms. All of these elements are present at NewYork-Presbyterian. It's why our patients do so well and among the reasons leading to the Hospital's designation as a Comprehensive Stroke Center."

A radiologist with subspecialty training in interventional neuroradiology and endovascular neurosurgery, Dr. Meyers has for years championed the need for the development of technical standards and clinical guidelines for the field and served as chair

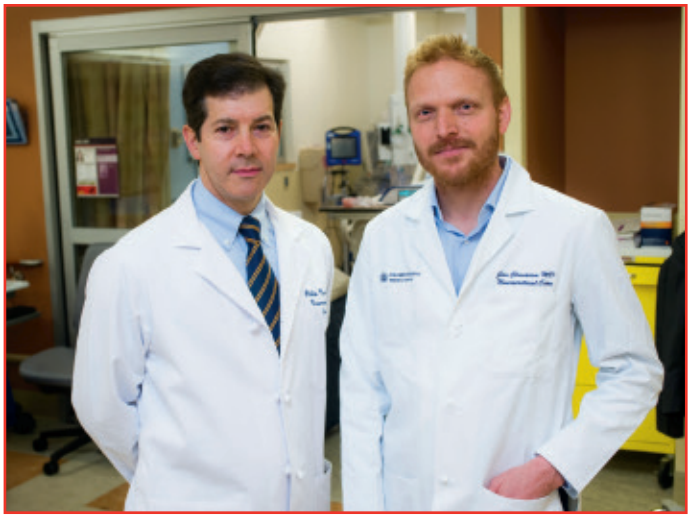
of the Society of NeuroInterventional Surgery's Committee on Guidelines and Standards. More recently, he and Dr. Sander Connolly served as members of the Writing Group commissioned by the American Heart Association/American Stroke Association to develop evidence-based recommendations for the management of patients with unruptured intracranial aneurysms, which were published in *Stroke* in 2015.

A Focus on Neurointensive Care

"In the past decade, there has been major recognition that care of patients with neurological injury is unique and should be led by specialized teams," says **Halinder S. Mangat, MD**, Medical Director of the Neurological Intensive Care Unit at NewYork-Presbyterian/Weill Cornell. Dr. Mangat provides specialized expertise in advanced clinical neurovascular physiology monitoring techniques using invasive devices such as cerebral oximetry and cerebral microdialysis, which measure chemicals released into the brain.

"Scientific evidence shows that patients with neurological injuries have better outcomes when cared for on a dedicated unit," notes Dr. Mangat. "When patients are unconscious and ventilated, we can perform a number of assessments in addition to EEG monitoring to determine their condition and whether there has been a change in status. If a patient is in a deep coma, we can use more aggressive monitoring that involves placing probes in the brain to look at cerebral blood flow, intracranial pressure, and oxygen levels. Few hospitals have this capability to look at brain metabolism in real time."

"Our Neuro ICU was one of the first of its kind in the country to provide neurosurgical and neurological expertise for the sickest of patients," says **Jan Claassen, MD, PhD,** Medical Director of the Neurological ICU and Director of Critical Care Neurology at NewYork-Presbyterian/Columbia. Dr. Claassen is an internationally recognized expert in neurological intensive care with particular expertise in brain hemorrhages. "We work incredibly close with neurosurgery, neurology, and interventional radiology. A lot of the care that we provide is aimed at minimizing secondary worsenings. If you can imagine a patient in a coma, there might be a storm going on in their brain, but you don't see it. We want to detect any changes as soon as possible.



Dr. Philip M. Meyers and Dr. Jan Claassen

"For example," continues Dr. Claassen, "a hemorrhagic stroke patient with a subarachnoid hemorrhage may develop a vasospasm. You often can't detect this in a poor grade patient, and it significantly impacts outcome. We have devised a number of monitoring techniques, non-invasive as well as invasive, to detect this complication in real time in order to intervene and prevent damage from occurring. We feel it is important for local physicians and local emergency rooms to know that we have a team capable of supporting their complex stroke patients through the more advanced care that NewYork-Presbyterian offers."

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NIH StrokeNet Trials

NewYork-Presbyterian, in association with Columbia University Medical Center and Weill Cornell Medicine, is one of 25 sites that form the NIH StrokeNet consortium responsible for implementing multicenter NIH-funded stroke clinical trials. Our site has enrolled more patients in StrokeNet-related trials than any other center.

CREST-2: Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis CREST-2 consists of two multicenter trials of carotid revascularization and intensive medical management in patients with asymptomatic high-grade carotid stenosis. One trial will investigate endarterectomy versus no endarterectomy and the second trial will evaluate carotid stenting with embolic protection versus no stenting.

DEFUSE 3: Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3 This study will evaluate the hypothesis that FDA cleared thrombectomy devices plus medical management leads to superior clinical outcomes in acute ischemic stroke patients at 90 days when compared to medical management alone. Endovascular treatment will be initiated between 6 and 16 hours after last seen well.

iDEF Trial: Intracerebral Hemorrhage Deferoxamine Trial Blood in the brain after a brain hemorrhage contains iron, which damages the brain. Deferoxamine mesylate or deferoxamine is a drug that removes iron. This study will evaluate whether removal of iron will reduce the effects of the brain hemorrhage and whether treatment with deferoxamine mesylate is of sufficient promise to pursue a larger clinical trial to examine its effectiveness for intracerebral hemorrhage.

MISTIE III: Minimally Invasive Surgery Plus rtPA for ICH Evacuation MISTIE is a series of clinical trials evaluating approaches to quickly remove an intracerebral hemorrhage (ICH) from the brain. The MISTIE III trial will evaluate the treatment of ICH with minimally invasive surgery and intermittent dosing of the clot-busting drug alterplase, a recombinant tissue plasminogen activator (rtPA). The study premise is that by removing the blood clot faster, injury to the brain will be reduced and the patient's long-term prognosis will improve.

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NeuroNEXT

RHAPSODY: A Multicenter, Phase II Study of 3K3A-APC with tPA in Ischemic Stroke Currently, the only approved treatment in the U.S. for ischemic stroke is a drug called recombinant tissue plasminogen activator (rtPA or tPA), indicated for intravenous administration within three hours of onset of the stroke. The drug is designed to break down blood clots to restore blood flow to the brain. In some patients, however, tPA can cause internal bleeding and other complications. This multicenter, Phase II study uses a continual reassessment method to determine the safety, tolerability, and activity of 3K3A-APC, a recombinant variant of human activated protein C (APC), in combination with tissue plasminogen activator (tPA), in subjects with moderately severe acute hemispheric ischemic stroke. The cytoprotective properties of 3K3A-APC may be useful in protecting ischemic brain tissue from further damage, while avoiding an increase in the chance of treatment-related bleeding.

The study intervention will be administered as a 15-minute infusion every 12 hours for up to 5 infusions. Four dose levels will be considered for this trial. Approximately 100 participants, ages 18 to 80 years old, will be enrolled and followed for 90 days.

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Mobile Stroke Treatment Unit Hastens Early Intervention

With major advances in prevention and treatment, stroke has moved from the third to the fifth leading cause of death in the United States. "The single greatest obstacle we have for improving on this even further is that most people who develop symptoms of a stroke do not get to the hospital fast enough in order for them to receive the kinds of effective treatments that we have now," says **Matthew E. Fink, MD,** Neurologist-in-Chief, NewYork-Presbyterian/Weill Cornell. "We know that with every delay in treatment, whether with tPA or endovascular therapies, there are diminishing returns in recovery potential."

In October 2016, NewYork-Presbyterian launched the first Mobile Stroke Treatment Unit on the East Coast. NewYork-Presbyterian's Emergency Departments have had systems in place for years to expedite stroke care once the patient reaches the hospital, resulting in response times from evaluation to treatment that are among the best in the country. "What we realized is there is still an issue with timeliness of patients receiving time-sensitive treatment," says Dr. Fink. "Often it's because patients are unsure of their symptoms and wait and see. This waiting then results in failure to make the most of the opportunity for early intervention. So we have been trying to figure out what we can do to shorten that time interval."

"When you think about emergency medical services and you think about the history of how ambulances work in New York City, it's always about how quickly an ambulance shows up and how quickly they can bring the patient to the emergency department," says **Jeffrey S. Bokser**, Vice President, Safety, Security and Emergency Services for NewYork-Presbyterian. "What we're looking to accomplish with the Mobile Stroke Treatment Unit really transforms that model to where the emergency department is brought to the patient – an ED on wheels so to speak. By doing this it allows us to save upwards of 30 minutes in time to treatment for patients who may be having a stroke."

Taking a page from the work of German neurologists Alexander Kunz, MD, Martin Ebinger, MD, and their colleagues, who had implemented an ambulance-based thrombolysis program years ago, Dr. Fink and his colleagues began considering this approach. "The published studies of Drs. Kunz and Ebinger demonstrated that they were able to shorten the time to treatment by an average of 25 minutes. That's considerable and if you extrapolate what that means in terms of patient outcomes, that reduction in time to treatment would translate into a very significant benefit to the patients. Consider that 1.9 million brain cells are lost for every minute of delay and multiply that by 25 minutes – you're saving a lot of brain cells."

Dr. Fink notes that in the European model of emergency medicine, doctors go out on ambulances as a matter of course, typically not so in the U.S. "The first mobile stroke unit in the country was established by the University of Texas Health Science Center in Houston in 2014 and is very successful. Others have since been established but none existed on the East Coast."

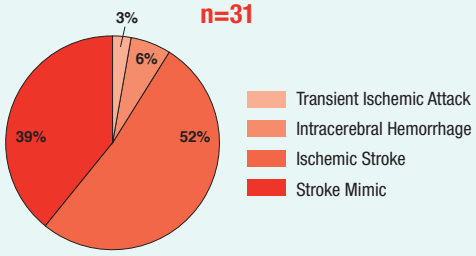
(continued on page 6)

Dr. Matthew E. Fink, Neurologist-in-Chief, NewYork-Presbyterian/Weill Cornell; Dr. Steven J. Corwin, President and CEO, NewYork-Presbyterian; James P. Booth, Chief, EMS Operations, New York City Fire Department; Jeffrey S. Bokser, Vice President, Safety, Security, and Emergency Services; and Dr. Olajide A. Williams, Director of Acute Stroke Services, NewYork-Presbyterian/Columbia

Mobile Stroke Treatment Unit October 2016 to January 2017 At a Glance

Days of Service	80
Unit Deployments	130
Patient Transports	31
rtPA Administration	8
Endovascular Therapy	2
Intracerebral Hemorrhage	2

Final Diagnosis of Patients Transported n=31



Case Study

While in the waiting room for a routine doctor's appointment, a 90-year-old female developed acute left-sided weakness and dizziness. The Mobile Stroke Treatment Unit was called and its team performed an initial evaluation. The patient's CPSS equaled arm drift only and NIHSS was 4 (minor stroke). Her left leg could not be lifted antigravity. The patient was brought onto the Unit and a head CT was obtained. Her symptoms continued to improve, but she still had left leg weakness. tPA was administered 55 minutes (golden hour thrombolysis) from the time her symptoms appeared. Her mRS was 0 at discharge, and the patient was discharged home with services.

Treatment Course

Onset of symptoms to 911 call	5 min
Dispatch to arrival of Mobile Stroke Treatment Unit	4 min
Arrival of Unit to CT completion	28 min
Unit arrival to rtPA	46 min

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Mobile Stroke Treatment Unit Hastens Early Intervention

(continued from page 5)

"We spent a lot of time with the Houston program looking at how they deployed the program in their geography," adds Mr. Bokser. "We also studied the lessons learned from their experience and then incorporated that into our model. The geography of New York City, the streets of New York, and the way the New York City 911 system operates is very unique. So, we had to adapt the implementation of our Mobile Stroke Treatment Unit to meet the needs of our region."

With the support of the Fire Department of New York and key stakeholders, NewYork-Presbyterian mobilized the team, custom built the ambulance complete with a specially designed portable CT scanner, developed the protocols, and carried out training and simulation drills.

Dr. Fink and **Babak B. Navi, MD, MS,** Medical Director, Stroke Program, NewYork-Presbyterian/Weill Cornell, and **Richard P. Mayeux, MD, MSc,** Neurologist-in-Chief, **Randolph S. Marshall, MD, MS,** Chief, Division of Stroke and Cerebrovascular Disease, and **Olajide A. Williams, MD, MS,** Director, Acute Stroke Services, at NewYork-Presbyterian/Columbia, collectively lead the team of stroke care specialists assigned to the unit. Two experienced, specially trained paramedics, a CT technologist, and a neurologist who can administer tPA in the ambulance are on board for each call. Imaging from the CT scanner can be transmitted wirelessly to be reviewed by a neuroradiologist on site. A future goal is to incorporate real-time teleconferencing between the doctors at the hospital and the medical team and patient in the ambulance.

"With a CT scan, laboratory information, and a neurologist's examination of the patient completed in the unit, a diagnosis or rule-out of stroke can be made quickly and guide decisions that can be carried out at the hospital, hastening time to additional testing and care that might be needed," says neurologist **Michael P. Lerario, MD,** who serves as Medical Director of the Mobile Stroke Treatment Unit. "We can call ahead to the hospital and let them know that we're bringing in an ischemic or hemorrhagic stroke patient, the time of onset of stroke, whether the patient was given tPA, and if the patient could be a candidate for endovascular therapy and to alert the interventional neuroradiology team…all this en route before the patient even gets to the door."

Importantly, the new program has been implemented in partnership with the Fire Department of New York, and is tied into the 911 system. "This new unit works closely with FDNY paramedics, EMTs, and firefighters on some of the most serious medical calls the Department responds to, increasing the level of pre-hospital care our patients receive, preventing further long-term effects due to patients who have suffered a stroke, and potentially saving many more lives," says New York City Fire Department Commissioner Daniel A. Nigro.

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