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neuroreport

Carolinas HealthCare System

TOPICS:

Neurotrauma Team Advances TBI Treatment

Home to the region's only Level I trauma center, Carolinas HealthCare System provides the highest quality of care for a large volume of both adult and pediatric neurotrauma patients. In its commitment to continue raising the bar, the team of neurosurgeons, trauma surgeons, critical care physicians and rehabilitation specialists has been tracking patient treatment and associated outcomes through quality improvement and research initiatives.

EMBEDDING CARE PATHWAYS AT THE POINT OF SERVICE

The multidisciplinary neurotrauma team strives to provide the best evidence-based care to patients with traumatic brain injury (TBI). To support this process, the team recently developed its own evidence-based TBI care pathways and incorporated them into the Carolinas HealthCare System electronic medical record platform. Data collection from daily patient interactions was the first step of the initiative, followed by analysis to determine best practices for specific patient populations. The objective is to embed the pathways into the EMR, allowing providers to access the information at the point of service. Even after beta testing is complete, the team will continue to gather and analyze data, providing a constant feedback loop to iteratively improve care quality.

"Through this data collection and analysis, we are uncovering opportunities to improve our processes and change our care paradigms, realizing the Lean Six Sigma model for care optimization," said Anthony Asher, MD, FACS, co-medical director of the Carolinas HealthCare System Neurosciences Institute. "Embedding these pathways within not only our electronic system but also patient care is critically important, as we turn the health system into a true learning system."

Asher recognizes that an important balance is necessary when establishing care pathways, to ensure standards have been outlined but physician judgment is valued.

"Adopting care pathways doesn't take away from physician autonomy, nor should it," said Asher.

> "Alternatively, these processes allow us to collaboratively decide on the best care, provide a platform on which to evolve care, and allow a way to potentially modify care in individual settings."
>
> -Anthony Asher, MD, FACS

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We must, however, come to some conclusions about a few methods to guide treatment, instead of 100 different physicians doing things 100 different ways. We will never be able to develop true value in healthcare with such a haphazard approach."

REGISTRIES EXPAND TBI KNOWLEDGE BASE

The neurotrauma team is also utilizing data collection for key research registries. The TBI Research Registry helps the team determine optimal TBI treatment and connect patients with important community and clinical resources. The Mild Traumatic Brain Injury (mTBI) Registry tracks three aspects of patient status – blood biomarkers, cognitive function and physical function – at the time of injury and numerous follow-up intervals, with the goal of illuminating the best methods of mTBI management.

As the team continues to expand its TBI initiatives, the ultimate objective remains the same. "Our goal is to provide comprehensive care after someone has survived the initial injury, maximizing their functional recovery," said Lori Grafton, MD, director of the brain injury rehabilitation program at Carolinas Rehabilitation.

A Commitment to Collaboration

NEUROSURGEONS CELEBRATE EXCEPTIONAL NURSING STAFF

Surgeons from Carolinas Neurosurgery and Spine Associates (CNSA) recently presented the neurosurgical unit care team with a sculpture to recognize their outstanding work.

At Carolinas Medical Center in Charlotte, NC, cranial and spinal surgery patients are cared for by a team of skilled nurses who consistently go above and beyond. Ensuring this effort does not go unnoticed, the CNSA surgeons recently gifted the nursing staff with an artistic brain and spinal cord sculpture that now resides in their main nursing station. "On a day-in, day-out basis, these nurses are providing excellent patient care," said Domagoj Coric, MD, chief of neurosurgery and medical director of the neurosurgical intensive care unit (ICU) at Carolinas Medical Center. "In addition to being highly competent, they are dedicated and hardworking, which creates an important combination for keeping patients happy and generating good outcomes."

The nursing team has exceeded the high expectations that accompany working with this patient population, specifically, the many complex spinal and cranial surgical cases that require a level of neurosurgical nursing care not necessarily available at other institutes, Coric noted.

"You expect a certain above-average level of competency, but the simple fact is that they constantly go beyond even that, striving for excellence, a representation of their dedication and their attention to detail," said Coric. "The detail could be the difference between a complication and not having a complication – it can be life-altering."

"The nursing staff is so good other services want to put patients on our floor. They realize that our staff is a cut above, and that's the same concept we tried to express through the donation of the sculpture."

The CNSA surgeons wanted to highlight the nurses' expertise in the sculpture design. While both staffs – surgeons and nurses – celebrate teamwork at various events throughout the year, Coric noted that the sculpture provides lasting recognition.

"At the end of the day, it's all about our patients, and it is very important that our nurses take it upon themselves to treat each patient like a family member," he said. "This sculpture is a small token of our appreciation for that."

Trigeminal Neuralgia Program Supports Patients in Pain

Anthony Asher, MD

Unbearable pain from speaking, eating and touching the face is the everyday experience of a patient with trigeminal neuralgia. Seeking to reduce this pain and return patients to a productive life, the trigeminal neuralgia program at the Carolinas HealthCare System Neurosciences Institute treats these patients with tailored care that includes medical, percutaneous and surgical interventions.

A RARE BUT DEBILITATING CONDITION

Trigeminal neuralgia is a disorder of the fifth cranial (trigeminal) nerve, which supplies sensation to the face and helps control the chewing muscles. The condition is usually caused by an artery that compresses the trigeminal nerve, causing it to misfire and result in intense episodic pain. Touching the face, especially when eating, brushing the teeth, applying makeup, or shaving, often triggers this pain. Although trigeminal neuralgia is rare, its disease burden is heavy. Patients with the disorder experience a significantly low quality of life due to the severe pain.

"Trigeminal neuralgia is a disorder that is among the most incapacitating pain disorders known to man," said Anthony Asher, MD, FACS, co-medical director of the Institute and the only provider in the Southeast offering comprehensive care for trigeminal neuralgia patients.

> "Individuals with this condition are not able to participate in a productive lifestyle, because the pain is ruling their lives. It is important to recognize that this group of individuals really is in need of advanced therapies, and the good news is, we are able to offer these."
>
> -Anthony Asher, MD, FACS

TREATMENTS ACROSS THE SPECTRUM

Asher primarily utilizes four different treatments when working with trigeminal neuralgia patients: medication, percutaneous rhizolysis, stereotactic radiosurgery and microvascular decompression. Medication with an anticonvulsant, such as carbamazepine, is generally the first-line therapy. For patients who are refractory to medical therapy or have breakthrough pain, one of the three interventional therapies is used.

Microvascular decompression is considered the gold standard for trigeminal neuralgia and is used in patients who are healthy and have a good functional status.

According to Asher, approximately 80 to 90 percent of patients experience long-term pain relief with this therapy, which involves surgically implanting a sponge between the trigeminal nerve and the compressing artery. If a patient has medical issues precluding surgery, percutaneous rhizolysis and stereotactic radiosurgery provide less-invasive options, with the latter being the treatment most often used for older patients. Patient age, preference and previously used therapies all act as important other factors when determining the proper treatment.

BUILDING SUCCESS, ONE PATIENT AT A TIME

Across Asher's nearly 20 years of treating trigeminal neuralgia patients, he has repeatedly seen patient success stories, where the individual has sustained pain relief and returned to a productive lifestyle. A less obvious but no less important success is providing patients with the correct diagnosis.

"Because trigeminal neuralgia is relatively rare, recognizing it for what it is can sometimes be difficult," Asher said. "It can be confused with other syndromes, and you need to be seeing a significant volume of trigeminal neuralgia cases to correctly diagnose it. Some of the other facial pain syndromes can actually be made worse by the standard trigeminal neuralgia treatments, so it is imperative to have the proper diagnosis."

For example, post-herpetic neuralgia, cluster headaches and TMJ all share overlapping symptoms, complicating diagnosis. Further, many patients with trigeminal neuralgia will undergo an MRI to ensure that a tumor or multiple sclerosis is not the source of their pain.

Asher adds that, in addition to skilled recognition of the disorder, his many years treating this patient population have allowed him to provide care with an appropriate surgical threshold that is tailored to each individual, achieving pain relief and returning patients to a higher quality of life as quickly as possible.

Clinical Trials Aimed at Increasing Therapy Options for MS, ALS

Two ongoing studies at the Carolinas HealthCare System Neurosciences Institute – one for a drug in phase III development and the other for a humanitarian-exempted device – are currently accepting participants.

NEW DISEASE-MODIFYING AGENT FOR SECONDARY PROGRESSIVE MS

The Multiple Sclerosis Center at the Carolinas HealthCare System Neurosciences Institute has been recognized as a leader in the research and treatment of MS, having participated in more than 90 clinical trials in the past 20 years. Continuing this commitment to research, the center is currently involved in a Phase III clinical trial aimed at expanding treatment options for patients with secondary progressive multiple sclerosis (SPMS).

The EXPAND trial, sponsored by Novartis, is a multi-center, randomized, double-blind, parallel-group, placebo-controlled study that examines the use of Siponimod (BAF312) in patients with SPMS. Designed to provide efficacy, safety and tolerability data for Siponimod compared to placebo, the study involves administering an oral 2-mg tablet once daily.

"There are not a lot of medications approved for treatment of SPMS, and that limits the available comparators for this study, which ultimately leads to the use of a placebo," said Maryanne Burdette, RN, BSHA, MS, the study's clinical coordinator. "The only drug specifically FDA-approved for SPMS, mitoxantrone, has a black box warning because of its cardiotoxicity and the risk of developing secondary acute myeloid leukemia, which limits an individual's lifetime dose."

The study's primary outcomes measure is a delay in time to 3-month confirmed disability progression, as measured by the Expanded Disability Status Scale (EDSS). Secondary outcomes measures include: a delay in worsening of the timed 25-foot walk test; a reduction in the increase in T2 lesion volume; a reduction in the frequency of confirmed relapses; evaluation of the safety and tolerability of siponimod.

The Neurosciences Institute plans to enroll eight to 10 ambulatory patients aged 18-60 years (both male and female) who have a diagnosis of SPMS and an EDSS score of 3.0 to 6.5. Patients will be followed for 23 to 42 months (maximum 60 months) across the study period, which ends around March 2017. Approximately 1,500 patients will be enrolled in the study at 250 sites worldwide. Inclusion criteria include a prior history of relapsing remitting MS and no corticosteroid treatment within three months of entering the study.

"As a phase III trial, this study is building on years of data already established for this drug," said Jill Conway, MD, MA, principal investigator for the EXPAND study and medical director, MS Center Neurosciences Institue. "We will continue, however, to learn a lot about the medication's efficacy, safety, and tolerability. The hope is that this medication will be approved as a treatment for secondary progressive MS."

Siponimod is an oral selective modulator of sphingosine 1-phosphate receptor subtypes 1 and 5. Designed to allow greater retention of lymphocytes within the peripheral lymph nodes (thus avoiding their release and migration into the central nervous system), the compound has greater selectivity than the current-generation sphingosine 1-phosphate receptor modulator, fingolimod (Gilenya®), also manufactured by Novartis, which has been FDA approved for relapsing-remitting MS. Siponimod was previously tested in the phase II BOLD study.

IS YOUR PATIENT A CANDIDATE?

For more information about this clinical trial, call 704-446-1925. For information about other clinical trials at Carolinas HealthCare System Neurosciences Institute, visit CarolinasHealthCare.org/Neurosciences-Clinical-Trials or call 704-512-5603.

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Benjamin Brooks, MD

DIAPHRAGM PACING SYSTEM TESTED FOR PATIENTS WITH ALS

As a leading provider of neuromuscular care, both nationally and internationally, the Carolinas Neuromuscular/ALS-MDA Center at the Carolinas HealthCare System Neurosciences Institute participates in research on treating, evaluating and managing ALS patients throughout their disease process.

Currently, the center is participating in a multi-center, randomized, controlled clinical trial that evaluates the use of the NeuRx® Diaphragm Pacing System™ (DPS) in patients with ALS. The study will be accepting its first participant this summer, with plans to ultimately enroll nine patients out of a study-wide total of 180 at 20 centers. Participants will be randomized in a 1:2 ratio to receive either the standard of care alone (non-invasive ventilation [NIV]) or NIV plus the DPS. Survival and quality of life will be assessed as primary and secondary outcome measures, respectively.

The DPS is a percutaneous diaphragm muscle simulation system. The technology's four electrodes are laparoscopically implanted in the diaphragm while a fifth is inserted under the skin. Patients turn the device on and off with an external pulse generator. The device settings can only be changed by trained personnel.

"The number one reason ALS patients die is respiratory failure, because the muscles don't allow them to breathe and the diaphragm often atrophies from using NIV and other similar treatments," said Cynthia Lary, RN, BS, a research nurse coordinating the study. "With this study, the DPS is designed to not only help them breathe, but also keep their diaphragm stimulated. So, we'll see if it, in fact, keeps their diaphragm in better shape."

The study's inclusion criteria include a diagnosis of sporadic or familial ALS (diagnosed as definite, probable, or possible, according to revised El Escorial criteria), evidence of hypoventilation (based on maximal static inspiratory pressure or forced vital capacity), and the ability for both hemi-diaphragms to be stimulated. Participants must also have been either on a steady dose or not taking riluzole for at least 30 days.

The device, which is manufactured by Synapse Biomedical, has been approved for use in spinal cord injury since 2008, and was granted humanitarian use exemption for use in ALS by the FDA in September 2011. The exemption is based on limited information about how effective the device is in humans. This study is being conducted to provide more information about the effectiveness of the device.

"It's difficult for ALS patients, because they have limited treatments available," said Benjamin Brooks, MD, principal investigator for the DPS Study and medical director, Carolinas Neuromuscular/ALS-MDA Center. "Our center has done excellent work extending their lifespan with the standard of care, but regardless, every trial that comes along, we hope that it will help them."

IS YOUR PATIENT A CANDIDATE?

For more information about this clinical trial, call 704-446-6063. For information about other clinical trials at Carolinas HealthCare System Neurosciences Institute, visit CarolinasHealthCare.org/Neurosciences-Clinical-Trials or call 704-512-5603.

Effective Cerebrovascular Care Rooted in Experience

Carolinas HealthCare System Neurosciences Institute offers comprehensive neurologic, radiosurgical, neurosurgical and endovascular care for all cerebrovascular conditions. The Institute offers around-the-clock access to seasoned experts who provide highly personalized medicine. As a major referral center – including one of the Southeast's highest treatment volumes for aneurysms and arteriovenous malformations (AVM) – the Institute serves patients from across the country with a multi-disciplinary team.

EXPERIENCE UNDERLIES COMMITMENT TO WORLD-CLASS CARE

The cerebrovascular program's team-oriented approach brings together physicians, physical therapists, occupational therapists, speech therapists, counselors, a dietician and an exercise consultant, resulting in a breadth of knowledge that is matched only by its depth.

"You'd be hard-pressed to find a practice where there are people with more experience," said Joe Bernard, Jr., MD, director of neurointerventional services at Carolinas Medical Center. "Some of my colleagues here have treated 2,000 aneurysms across their career, [while] others have experience with a considerable number of vascular malformations, including in children. Our practice encompasses trained, experienced, senior-level providers."

As evidence of this experience, the cerebrovascular program treated 2,726 patients with stroke and transient ischemic attacks (TIA) in 2012. Bernard adds that the Institute is not only a major referral center for stroke and TIA, but also for aneurysms, AVMs and spinal vascular malformations. The Institute further provides care for subarachnoid and cerebral hemorrhage, moyamoya disease, dural arteriovenous fistula, carotid and vertebral dissection, and fibromuscular dysplasia.

HARNESSING DIVERSE PHYSICIAN EXPERTISE

The Institute's board-certified cerebrovascular specialists include physicians trained in neurological, radiosurgical, neurosurgical and endovascular treatments. Because of this varied practice expertise, patients receive the most individualized care based on their disease characteristics and personal risk factors.

"The nice thing about having a large practice with a broad talent base is that you can provide the procedure that is best for the patient," said Bernard. "I might see a patient who comes in to see me because catheters are less invasive, but I look at it and see that it's really better to treat open, [so] I walk him down the hall to my partner, who provides that."

The program's neurosurgeons and neurointerventionalists offer coil and stent embolization, flow diversion, mechanical thrombectomy, carotid endarterectomy, and aneurysm clipping. To provide wholly tailored care, the team also combines treatments, often collaborating with Southeast Radiation Oncology and Levine Cancer Institute. For example, a patient may undergo embolization or preoperative gluing of an AVM along with both surgery and stereotactic radiosurgery.

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SERVING AS GUIDES IN AN EVER-ADVANCING CEREBROVASCULAR LANDSCAPE

Understanding the Institute's role as a major referral center, the program's specialists are eager to help referred patients. "We have 24/7, 365 availability, so patients can always be [treated] in rapid fashion – even as an outpatient – to have their care initiated," Bernard said.

Physicians on the cerebrovascular team also share their expertise with other hospitals. "We are called on to proctor at other hospitals, so we have been to at least 12 other facilities nationwide to help them do their first cases of certain procedures with a new device," said Bernard. "Those kinds of experiences set us apart, where we've used the device, are comfortable with it, and are helping other people get started."

As eager to learn as they are to teach, the cerebrovascular team regularly becomes involved in clinical trials. Currently, their work with the MISTIE III (see call out box) trial has allowed them to provide minimally invasive hematoma aspiration for hypertension hemorrhage and other bleeds.

MISTIE III

The MISTIE III trial (Minimally Invasive Surgery Plus rt-PA for ICH Evacuation Phase III) will include 500 subjects ages 18 to 80 in a randomized, controlled study of ICH patients who have a clot size of 30 mL or greater. Carolinas HealthCare System Neurosciences Institute will follow up to 10 patients who come into the emergency department, are admitted to the hospital and enroll in the year-long study. The trial will run from December 2013 through September 2018.

MS Center's New Clinical Expert:

Donna C. Graves, MD
MS Specialist

Carolinas Medical Center, part of Carolinas HealthCare System, is pleased to announce the arrival of Donna Graves, MD, to Carolinas Medical Center's Multiple Sclerosis Center. Dr. Graves will care for patients previously treated by Dr. Michael Kaufman as well as new patients, while working closely with Jill Conway, MD; Marie Moore, NP, and the rest of the MS Center staff to continue providing excellent care.

Upon receiving her medical degree from the Mercer University School of Medicine, Dr. Graves completed a neurology residency at St. Louis University. She went on to complete a demyelinating disease fellowship at University of Texas Southwestern Medical Center. Dr. Graves is board certified in neurology.

Dr. Graves served as assistant professor in the department of Neurology and Neurotherapeutics at UT Southwestern Medical Center and also worked as deputy director of the pediatric demyelinating clinic at Children's Medical Center in Dallas, TX. She is involved with The National Multiple Sclerosis Society, the American Academy of Neurology, and the Consortium of Multiple Sclerosis Centers.

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