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FDA Panel Unanimously Supports Benefits of New Epilepsy Treatment

Ryder Gwinn, M.D., Director of Epilepsy and Functional Neurosurgery, Swedish Epilepsy Center

The Swedish Neuroscience Institute was one of 32 centers that participated in a double-blind, randomized clinical trial to determine whether an implanted NeuroPace RNS® System device could reduce seizure frequency in adult patients with epilepsy. The device is the first significant new treatment for epilepsy since 1997.

At the conclusion of the study in 2010, NeuroPace sought approval for the device from the U.S. Food and Drug Administration (FDA). In February of this year, the FDA’s Neurological Devices Panel voted unanimously, with two abstentions, that the clinical benefits of the RNS System outweigh the risks of its use. The final decision by the FDA is expected this summer.

Treatment options for epilepsy include drugs, surgical resection and nerve stimulation. Whereas surgery remains the gold standard of treatment options, the RNS System provides new hope for patients who are not candidates for surgery, such as those with bilateral temporal lobe epilepsy, and for those who have failed medication.

The NeuroPace device consists of a neurostimulator, which is implanted in the skull and

Experience Counts When Treating Patients with Aortic Valve Stenosis

The Swedish Heart & Vascular Institute (SHVI) is one of the few places in the Pacific Northwest able to offer treatment options for patients with severe aortic valve stenosis – even those who are not candidates for open-heart surgery due to age, frailty or other co-morbidities. SHVI’s interventional cardiologists and cardiovascular surgeons have significant experience and expertise with both surgical and transcatheter aortic valve replacement (AVR).

The primary cause of aortic stenosis is calcification and narrowing of the valve, thereby limiting cardiac output. Aortic stenosis affects an estimated 5 percent of people age 75 and older. Valve replacement is the only cure for aortic stenosis; without it, 50 percent of these patients will survive less than two years after symptom onset.

Identifying the best option

“We have an AVR evaluation process based on a deep-seated collaboration among medical, surgical, nursing and ancillary specialties,” says Glenn R. Barnhart, M.D., chief of Cardiac Surgery and surgical director of the Structural Heart Program. “It is this comprehensive evaluation that ensures each patient is offered the best possible treatment option.”

Evaluations for surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) are similar. Studies include echocardiogram, cardiac catheterization, CT scan, pulmonary function testing and carotid artery ultrasound. Objective measures are used to evaluate frailty, a formal diagnosis encompassing strength, mobility, nutrition and tissue integrity. The assessment also includes the Society for Thoracic Surgeons (STS) risk calculator, a tool to help quantify mortality and morbidity risk due to major adverse events.

The majority of patients with severe aortic stenosis are deemed candidates for SAVR, which is typically performed as an open-heart

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connected to electrodes that are implanted directly onto the brain surface precisely where the seizures originate. The battery-operated neurostimulator continuously monitors brain activity. When the detector senses a seizure, the electrodes emit a pulse of energy designed to short circuit the seizure before it spreads throughout the brain.

Currently, vagus nerve stimulation (VNS) therapy is the only FDA-approved form of neuromodulation to treat epilepsy. Frequently, however, significant seizure reduction is not achieved with VNS.

Despite a more challenging population of patients implanted with (continued on next page)

**An Illustrated Case Report: Brain stimulation helps control seizures when nothing else can**

Ryder Gwinn, M.D., Director of Epilepsy and Functional Neurosurgery, Swedish Epilepsy Center

**Childhood:** As a baby, Brian was late walking and in meeting other developmental milestones. He had mild right-side weakness, which led to a diagnosis of cerebral palsy. Brian had his first seizure at the age of eight. An MRI showed an area of abnormal brain development in the left frontal lobe known as schizencephaly. For the next three decades his physicians tried every known antiepileptic drug. At times he was on five medications simultaneously. Nothing worked.

**Age 41:** Brian underwent an extensive evaluation at the Swedish Epilepsy Center at the Swedish Neuroscience Institute (SNI) to determine if he was a candidate for surgery. Testing included video EEG monitoring, neuropsychological testing, a Wada test, and an MRI of the brain tailored to identify abnormalities peculiar to patients with epilepsy. He also underwent an ictal SPECT and PET scan to identify the brain areas causing seizure activity.

The SNI epilepsy team developed a consensus recommendation that Brian would benefit from surgery. More precise localization of the seizure focus was performed using special platinum electrodes placed directly on the surface of the brain, which revealed seizures coming from an area adjacent to the developmental abnormality. Brian underwent surgery to remove the seizure focus. He initially did well following surgery; however, the seizures returned, but with different clinical features. Further trials of medications were unsuccessful. The seizures became more frequent, often occurring hundreds of times each day.

**Age 44:** In 2006 Brian underwent a SISCOM study and additional video EEG monitoring. Electrodes localized seizures to two areas in the left frontal lobe. The functions of the frontal lobe were mapped and it was determined that one area could be safely removed. The second area controlled right-arm movements, which made removal inadvisable. Following removal of the first area, Brian was seizure free for only four months.

**Age 45:** Brian developed episodes of right-hand twitching, progressing to daily motor seizures affecting the entire right side of his body. Knowing that further surgery was not advisable, Brian agreed to a NeuroPace RNS® System implant.

**Today:** Brian is now doing very well. His seizures have nearly stopped since the device was implanted. Every three to four months he occasionally will have arm tremors, which last for a few seconds and then go away. He has gone white-water rafting, and is able to take the bus and travel independently. Brian remains on medication, but now has a very positive outlook on his future.
A Measured and Disciplined Approach to Proton Therapy

Vivek Mehta, M.D., Medical Director, Centers for Advanced Radiation Therapy, the Swedish Cancer Institute

The emergence and increased availability of proton therapy for cancer patients has created considerable commentary and some controversy among leaders in radiation therapy. Some individuals claim the biological and physical characteristics of protons are so favorable that one day it might replace traditional radiotherapy altogether.

For more than 76 years, the Swedish Cancer Institute (SCI) has been a leader and pioneer in developing, testing and adopting new radiotherapy technologies. In regards to proton therapy, we have chosen to take a measured and disciplined approach to how we incorporate this technology into the care of our patients.

Unlike traditional X-rays or photons, protons are charged particles. When they are accelerated, they can deposit most of their energy in a specified depth range – called the Bragg Peak. There is speculation that this characteristic will enable more energy to be deposited at the cancer and less energy deposited in surrounding normal tissues; thereby, hopefully reducing toxicity and side effects.

While I am attracted to these theoretical benefits, it is in the best interest of our patients for us to rigorously assess whether:

- The plans created on a proton machine are better dosimetrically
- The patient will realize a clinical benefit
- We are cognizant of the costs relative to the benefits for the patient and for society

Evaluating dosimetry

One of the limitations of delivering proton therapy is that the technology does not account for geometric or positional variations of the target or normal tissues, which can occur due to movement or setup uncertainty. Therefore, to ensure the target is not missed due to these variables, the area to be treated is often larger. In contrast, photon or X-ray radiotherapy utilizes more sophisticated treatment planning, more angles and more intensity modulation to achieve higher doses in smaller, more specified volumes. Additionally, X-ray or photon technology incorporates “image guidance,” which improves delivery precision and accuracy, and provides important information about changes in the shape and size of the target.

New Epilepsy Treatment

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the RNS System, long-term results showed a significant reduction in seizure frequency post implant of 44 percent at one year and 53 percent at two years. Some patients have had no seizures or only a rare seizure since implantation.

If the FDA approves this therapy, the Swedish Neuroscience Institute will be the only center in the Pacific Northwest to offer treatment with the RNS System. For more information, call 206-320-3852.

The jury is still out on improved outcomes

In 2011 the Advisory Committee of the American Registry of Radiation Technology issued a report indicating that for a few tumor sites (pediatrics, ocular and chordomas of the skull base), proton therapy is potentially advantageous. For the majority of sites, however, the report indicated there was no conclusive data, or outcomes were very similar to other radiation therapies.

Nationwide, proton therapy has been widely adopted for prostate cancer, with prostate cancer accounting for approximately 75 percent of all proton therapy treatments. And yet, according to the Advisory Committee’s report, the results are no better than with other radiation therapy platforms. Some people have suggested that consideration in treating patients with prostate cancer is primarily economic. The investment in a proton facility is substantial. In many instances, to build a center might cost more than $100 million. The only way to cover those costs is to treat a commonly diagnosed cancer, such as prostate cancer.

A different approach at the SCI

At the Centers for Advanced Radiation Therapy at the SCI, we believe in advancing technology in a measured and disciplined

When to Refer to Swedish

(continued on next page)
Please Join Us at the Lytle Center VIP Open House

The providers and staff of The Lytle Center for Pregnancy & Newborns cordially invite you to see where life’s greatest journey begins. We hope you can join us in celebrating the center’s opening at our special Providers and Staff Open House on Friday, Aug. 2, from 3 to 8 p.m., at Swedish/First Hill in Seattle.

The Lytle Center is a dedicated resource for moms, newborns and families during the first few weeks following delivery. It will be open seven days a week, with weekday evening hours beginning July 31. Services at the center include:

- Clinical appointments for new moms and well-baby checkups shortly after delivery
- Clinical and social work support for postpartum mood disorder
- Breastfeeding support from certified lactation nurse consultants
- Breast pump rentals and other lactation supplies
- Childbirth, parenting and family education classes
- Fitness classes for pregnant and postpartum moms
- Support groups for expectant parents, siblings and grandparents
- Baby changing and weighing station
- Dedicated retail with necessities for childbirth, parenting and wellness
- Happy Birth Day get-acquainted tours and pre-birth tours at Swedish/First Hill

For more information about The Lytle Center for Pregnancy & Newborns, go to www.swedish.org/thelytlecenter or call 206-386-BABY (206-386-2229).

The Lytle Center Provider and Staff Open House

When: Friday, Aug. 2, from 3 to 8 p.m.
Where: 747 Broadway, Seattle, Wash. 98122. The entrance is located on Cherry Street, between Broadway and Minor Avenue.
Parking: Broadway parking garage, located at 747 Broadway

Please let us know you will be attending by calling 206-386-6797 or going online to www.swedish.org/TLCOpenHouse.

Surgical Options for Gallbladder Patients

Over the years technology has advanced the art of surgery, allowing surgeons to consider more than one technique. Thus is the case with cholecystectomy – and with the expanding capability of surgeons at Swedish.

Until the early 1990s open surgery, requiring one four- to eight-inch abdominal incision, was the standard treatment for removing the gallbladder. As with any major surgery, the hospital stay and recovery can be lengthy, and limits to the patient’s activities extend for four to six weeks.

The laparoscopic cholecystectomy, which was first performed in 1987, replaced open surgery as the standard approach because of its multiple benefits. A lap chole typically requires four small (1-2½ cm) incisions. Ninety-five percent of lap chole patients go home the same day and resume normal activities within a week. The resulting overall reduction in direct-care costs is dramatic.

The newest technology is robotics and the Single-Site® Cholecystectomy. Using the da Vinci® surgical system, surgeons are able to remove the gallbladder through one, small incision in the umbilicus. Procedure time, risk of infection, length of stay, and reduced pain and blood loss are comparable to the laparoscopic approach.

“The 3-D visualization, 10-X magnification, dampened movements and extra degree of articulation compared to standard laparoscopy afford greater precision, which is especially helpful in our more complex cases,” says Ryan Martinez, M.D., a surgeon with Swedish Surgical Specialists. “While Swedish will continue to evaluate the overall benefits of the single-site platform, the clear benefit to the patient is a nearly invisible scar.”

Swedish is a regional center for performing – and teaching – robotic surgery, and has made da Vinci surgical systems available at three of its campuses (Edmonds, First Hill and Issaquah).

Surgeons with Swedish Surgical Specialists are skilled in all three approaches to cholecystectomy. For more information or to consult on a patient or seek a second opinion, please call 206-215-3500.

Proton Therapy

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way – using an approach that promotes evidence-based decisions, places the patient at the center of deliberations and ensures treatment choices that first and foremost benefit the patient. Currently, we are testing a proton treatment-planning system to evaluate in a systematic fashion which patients might benefit from this therapy. We also are actively involved in planning for the next generation proton therapy system that promises to overcome some of the current limitations of the existing systems.

We offer an extensive menu of radiation therapies because we know there often are a number of ways to treat a particular cancer and that the treatment decision needs to be personalized for each patient. An evaluation by one of our experts, assures a balanced and thoughtful review of all options available to the patient. We invite you to call us at 206-386-2323 to consult on a particular patient, to request a second opinion or to inquire about treatment locations and options, including proton radiation therapy.
Alexander Farivar, M.D.
Thoracic Surgery, Swedish Cancer Institute

Pectus excavatum, often referred to in lay terminology as “sunken or funnel chest,” is the most common chest-wall abnormality, with an incidence of one in every 300-400 births. In pectus excavatum, an abnormal growth of the cartilage between the ribs and sternum causes the sternal bone to pull inward, resulting in the chest’s concave appearance. As the child develops, pectus excavatum can contribute to chest discomfort, loss of endurance, and social embarrassment and isolation. If left untreated, the pressure the sternum places on the heart and lungs eventually can result in cardiac dysfunction and restrictive lung function.

Swedish Thoracic Surgery offers a minimally invasive, video-assisted procedure to correct this sternal defect in children ages nine and older, as well as adults. Swedish is the only facility in Washington that makes this procedure available to both children and adults of all ages. The surgeon will order a chest CT scan to calculate a Haller Index, an echocardiogram and pulmonary function studies to determine if an individual is a candidate for surgery.

The VATS Nuss procedure
With the patient under general anesthesia, the surgeon makes a small incision in the right chest wall and inserts a thoracoscope, allowing direct visualization. Through a second incision, the surgeon inserts a curved Nuss bar introducer under the sternum and exiting the left chest. The introducer facilitates the eventual passage of a curved Nuss bar. Adults may have two bars placed to help mold the less malleable sternum seen in the adult population.

Patients experience an immediate cosmetic improvement at the conclusion of the operation.

The VATS Nuss procedure, named after Dr. Donald Nuss who pioneered the procedure, is far less invasive than the open-chest repair that was previously championed as the primary treatment. The open procedure requires cutting the sternum and ribs, and removing a portion of the chest wall.

Patients who have the VATS Nuss procedure can spend up to five days in the hospital in order to receive catheter-based pain management and teaching about appropriate activities that will help prevent bar migration during the early postoperative period.

Presented here are pre- and post-operative photos of a 23-year-old patient who suffered from a severe pectus deformity (Figure 1), with decreased exercise tolerance, chest discomfort and persistent tachycardia. He had a successful and uneventful operation in which a Nuss bar was inserted by VATS and the sternum remolded. An improvement in appearance and reduction in tachycardia was noted at the conclusion of the operation (Figure 2).

When to Refer to Swedish

Swedish thoracic surgeons are available to evaluate children (age nine or older) and adults with pectus excavatum. Symptoms may include:

- Tachycardia
- Chest pain
- Shortness of breath upon exertion
- Loss of endurance
- Social embarrassment and isolation

To consult on or refer a patient, please call 206-215-6800.

Go to www.swedish.org/thoracicsurgery for more information about Swedish Thoracic Surgery and pectus excavatum repair.

Swedish Thoracic Surgery
1101 Madison Street, Suite 850
Seattle, WA 98104
Telephone: 206-215-6800
Fax: 206-215-6801

Go to www.swedish.org/thoracicsurgery for more information about Swedish Thoracic Surgery and pectus excavatum repair.
Eighty-five-year-old Tom Goldader was referred to us in July 2012 for aortic valve replacement. Mr. Goldader has a medical history that includes controlled hypertension, hyperlipidemia, interstitial lung disease with a history of asbestos exposure, stage III renal disease, moderate anemia, gastroesophageal reflux disease, unspecified hepatitis diagnosed in 1954 and non-insulin diabetes mellitus. His prescription medications include: levothyroxine, glipizide, rosuvastatin, amlodipine, carvedilol, meclizine and doxazosin. He has a family history of diabetes, heart disease and stroke. He has not smoked in more than 40 years and does not drink alcohol. His chief complaint was that he feels weak and gets short of breath with minimal exertion. He also reported getting dizzy during moderate activity and that he has had an episode of syncope.

In 2005, Mr. Goldader had stents placed in his left and right internal carotid arteries. TTE acquired during the next five years showed moderate calcification in the aortic valve leaflets with moderate aortic stenosis. In August 2010, a stress echocardiogram showed moderate-to-severe reduction in exercise capacity. The stress test was stopped due to a drop in systolic blood pressure from 160 to 134, blunted heart rate response and dyspnea.

In 2008 and again in 2010, Mr. Goldader underwent right and left heart catheterization and coronary angiography. By April 2012, TTE showed severe calcific aortic stenosis.

Our thorough evaluation of Mr. Goldader for aortic valve replacement began in July and continued through September. CTA showed severe ascending aortic calcification that was nearly circumferential in some areas, which precluded the possibility of reasonable acceptable risk for cardiopulmonary bypass in the aortic cross clamping. His STS risk score for mortality was 12.0 percent. His blood workup indicated significant abnormalities and he met the frailty threshold. His functional status was declining and he could not walk 100 feet without having to stop and rest.

The TAVR team carefully reviewed the results of all diagnostic studies. Cohort B Guidelines for Surgical AVR deemed him inoperable due to porcelain aorta. After extensive discussion, the team concluded Mr. Goldader would benefit from transfemoral TAVR. We also determined that his left iliofemoral arteries were suitable for access for the 23-mm Edwards SAPIEN valve. He was scheduled for TAVR in early October.

The procedure, which was performed under general anesthesia, included left femoral cutdown, right and left heart catheterization, balloon aortic valvuloplasty and transcatheter aortic valve replacement with the 23-mm Edwards SAPIEN valve.

At his one-month follow-up appointment, Mr. Goldader was doing extremely well with no chest pain. In fact, his wife complained that she was having trouble “slowing him down” and they were planning a trip to Palm Desert.

In May of this year we saw Mr. Goldader for his six-month follow-up appointment. Clinically he is doing very well with no chest pain, shortness of breath or syncopal complaints. He reported that his overall energy level is much improved. An evaluation showed the bioprosthesis is well positioned and functioning normally. He is being followed routinely by his cardiologist.
our TAVR program to encompass more previously untreated patients.”

The TAVR device comprises a balloon-expandable stainless steel frame with bovine pericardial tissue leaflets forming the valve. (Figure 1) Rather than opening the chest, the new valve is delivered via a catheter-based approach through a small incision in the femoral artery in the groin. (Figure 2) Once in place, the new valve properly controls blood flow. (Figure 3) The procedure typically takes two to three hours, and the hospital stay ranges from four to seven days. Postprocedure follow-up appointments are scheduled at one to two weeks, and one, three, six and 12 months, then annually.

In addition to the general AVR evaluation, an echocardiogram and CT scan of the chest, abdomen and pelvis are critical in the final determination that a transcatheter approach using the SAPIEN device is a viable option.

Dedicated and experienced resources

The Swedish TAVR program is an example of how the extensive catheter-based skills of interventional cardiologists and the surgical expertise of cardiothoracic surgeons come together to provide treatment alternatives where none existed previously. The SHVI’s dedicated TAVR team includes an echocardiographer, a cardiac anesthesiologist, a radiologist, cardiac nurses, and program and patient care coordinators. The team works seamlessly to initiate testing, evaluate the results and determine the best treatment option.

For more information about surgical or transcatheter aortic valve replacement and for a copy of the SAVR/TAVR Referral Form, go to www.swedish.org/TAVR. Please call 206-320-8100 to consult on a specific patient or to request a second opinion.

When to Refer to Swedish

Structural Heart/TAVR Program
Swedish Heart & Vascular Institute
550 17th Ave., Ste. 680
Seattle, WA 98122
Phone: 206-320-8100
Email: TAVRinformation@swedish.org
Fax: 206-861-8551

The Swedish Heart & Vascular Institute (SHVI) is one of the few medical centers in the United States that offers both conventional and transcatheter aortic valve replacement. Physicians may refer or request a consult anytime they suspect valvular heart disease or have a concern for a heart murmur. Referrals may include patients with:

- Suspected severe aortic stenosis
- Diagnosed aortic stenosis or exam finding of systolic murmur
- Related symptoms, such as the aortic stenosis triad of symptoms: chest pain, syncope or congestive heart failure

SHVI works closely with referring providers to facilitate consultations, and with patients – especially those traveling great distances – to coordinate appointment and evaluation scheduling. More information and a referral form are available online at www.swedish.org/TAVR. Please contact us at 206-320-8100 or TAVRinformation@swedish.org to consult on a patient or to seek a second opinion.

Swedish Health Services
Quick Reference

Ballard
5300 Talman Ave. N.W.
Seattle, WA 98107-3985
206-782-2700

Cherry Hill
500 17th Ave.
Seattle, WA 98122-5711
206-320-2000

Edmonds
21601 76th Ave. W.
Edmonds, WA 98026
425-640-4000

First Hill
747 Broadway
Seattle, WA 98122-4307
206-386-6000

Issaquah
751 N.E. Blakely Dr.
Issaquah, WA 98029
425-313-4000

Mill Creek
13020 Meridian Ave. S.
Everett, WA 98208
425-357-3900

Redmond
18100 N.E. Union Hill Road
Redmond, WA 98052
425-498-2200

Swedish Medical Group
600 University St., Ste. 1200
Seattle, WA 98101-1169
206-320-2700

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www.youtube.com/swedishseattle

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Case studies are provided with the consent of the patient or with personal health information removed or altered in order to protect the patient’s privacy.
CME Course Listing – September – November 2013

Physicians from across the region and around the world come to Swedish Medical Center’s Continuing Medical Education (CME) courses to learn about new research and innovative treatment techniques.

For times and locations, go to www.swedish.org/cme or call 206-386-2755.

Orthopedics Symposium for the Primary-Care Physician
Friday, Sept. 6

Intensive Update in Neurology, 2013
Thursday-Friday, Sept. 12-13

Telehealth: Improving Access to Healthcare
Friday, Sept. 20

17th Annual Pain Management Symposium: Sherlock and the Mystery of Pain
Friday, Sept. 27

Cardiology for the Primary-Care Provider
Friday, Sept. 27

11th Annual West Coast Colorectal Cancer Symposium
Friday, October 25

Transradial Approach: A Case-based and Hands-on Training Course
Friday-Saturday, Nov. 8-9

Diabetes Management Update 2013
Friday, Nov. 15

Controversies in Neurological Restoration: Clinical Strategies and Case Presentations
Friday, Nov. 22

Otolaryngology for the Primary-Care Provider
Friday, Nov. 22

Join our email list at swedish.org/CMEProfile

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and follow us on Twitter: twitter.com/SwedishCME

Swedish Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Newest Members of the Swedish Medical Staff

The following individuals joined Swedish during the second quarter of 2013. We invite you to view their online profiles at www.swedish.org/physicians.

Lisa Arnold, CNM (Midwifery)
Todd Baumeister, D.O. (Pain Management)
Tara Benkers, M.D. (Neurology)
Brett Daniel, M.D. (Family Medicine)
Aarti Deshpande, M.D. (Family Medicine)
Megan Dunn, CNM (Midwifery)
Katherine Mayer, M.D. (Family Medicine w/ Obstetrics)

Stephen Monteith, M.D. (Neurosurgery)
Raanan Odom, M.D. (Pediatrics)
Marvin Roman, M.D. (Family Medicine)
Kathryn Samaniego, Au.D. (Podiatry)
Joseph Simonetti, M.D. (Internal Medicine/Hospitalist)
Jo Walker, M.D. (Family Medicine)