

Stimulates Phrenic Nerve

Ventilators from page 1

no recollection of breathing, having been on a ventilator since he broke his neck at age 2.

The only failure was in a patient who turned out to have a nonfunctioning phrenic nerve as a result of his injury.

The phrenic nerve enervates the diaphragm and is therefore required for independent breathing. Theoretically, the technology could enhance breathing capacity of virtually any patient requiring a ventilator whose phrenic nerves are intact, said Dr. Onders, director of minimally invasive surgery at University Hospitals of Cleveland.

Moreover, the simple system frees many patients and their families from the expense, inconvenience, noise, and lifestyle restrictions associated with ventilator dependence, Dr. Onders said.

Four patients with ALS, also known as Lou Gehrig's disease, have received diaphragm pacing devices as well, and Dr. Onders characterized their progress as "very impressive."

The first three patients have doubled their life expectancy as calculated by the arc of decline in forced vital capacity, with their mean life expectancy rising from 6.2 months to 11.7 months and counting—none have died since receiving their pacers.

Their diaphragms are thicker, they are breathing more easily, and they report an improvement in their ability to talk. (The fourth patient with ALS has not had the pacing system long enough to quantify results.) One patient with ALS is currently using the diaphragm pacer 24 hours a day to breathe, although the device—deemed "investigational" by the FDA—is not intended as a life support system.

With ALS, the goal is to prevent the need for a ventilator by compensating for the death of motor neurons that inexorably deprive ALS patients of the ability to breathe.

Conditioning the diaphragm enhances its performance, just as muscles around the knee are strengthened following

surgery by use of a TENS unit, Dr. Onders explained. A hoped-for secondary goal in ALS would be to foster "collateral sprouting," the transference of tasks to adjacent motor neurons as the disease progresses.

"As one axon dies, the one next to it will take over for it," he said, describing a theory that has proved true in the extremities and may apply to motor neurons enervating diaphragmatic muscles as well.

During surgery to implant the pacer wires, the diaphragm of one ALS patient in Dr. Onders' study appeared striped, which also lends credence to the idea that stimulation could be used to tap into undamaged muscle and nerves.

"It was one of those 'Eureka!' moments during surgery," he said. "Parts of the muscle were denervated and parts were normal."

During fluoroscopy following surgery, ALS patients took "sniff" tests to determine how much of their diaphragms they could control during breathing, versus the degree of control the pacer signals had over their diaphragm muscles. Surprisingly, in one patient, the pacer could produce 2 cm of diaphragm movement

to the 1 cm she could control by sniffing.

The laparoscopic procedure costs approximately \$12,000 and is reimbursed by Medicare. The device currently made by Synapse Biomedical, a university-owned company, would cost approximately \$10,000.

Ventilators cost \$120,000 a year and reduce the average life expectancy of spinal cord injury patients by 13 years.

One of Dr. Onders' patients was Christopher Reeves. Two are former high school football players who suffered spinal cord injuries on the field.

Another lost her home in Hurricane Rita but did not panic in the power outage since she no longer needs her ventilator to breathe, and the pacer that conditions her diaphragm operates on a battery that lasts 2 weeks.

Dr. Onders said he has noted no decrease in potency of the device over time in patients with either spinal cord injuries or ALS; in fact, one spinal cord patient has used the device for more than 62 straight months.

"Our goal is to get people out into society more. We designed the whole thing to make it simple," Dr. Onders said. ■

CT Angiography Screens for Blunt Cerebrovascular Injuries

BY BRUCE K. DIXON
Chicago Bureau

ATLANTA — Computed tomographic angiography with a 16-channel detector can be used to accurately screen patients for blunt cervical vascular and cerebrovascular injuries, according to two studies presented at the annual meeting of the American Association for the Surgery of Trauma.

"Though ours was a relatively small study population and future studies are needed to focus on the accuracy of grading by CTA, this technology should be considered the screening standard for patients at risk of blunt cervical vascular injury," said chief author Alexander L. Eastman, M.D., of the University of Texas Southwestern Medical Center in Dallas. "The severe and unforgiving nature of an undiagnosed blunt cervical vascular injury presents a real problem. Given the large differences in treated and untreated stroke rates, the principle of screening and early detection is vital. Despite this, the definition of an ideal screening test remains controversial, [though] catheter arteriography remains the 'gold standard.'"

In previous head-to-head studies using less powerful scanners, CTA failed to match the performances of catheter arteriography (CA). When a new 16-channel machine arrived at Parkland Hospital, the Dallas researchers decided to put it to the test.

Data from all patients presenting to their level I trauma center at risk for blunt cervical vascular

injury were collected prospectively. During an 8-month period, each patient was evaluated with CTA and the findings confirmed with standard CA of the head, neck, and aortic arch.

Of more than 3,000 trauma admissions during 8 months, 148 patients were deemed at risk for blunt cervical vascular injury. A total of 135 patients received both CTA and CA, and 13 received CTA only, due primarily to patient rejection of CA and discharge prior to CA. Among 41 patients, 43 blunt cervical vascular injuries were identified, yielding an overall incidence of 1.4% and an incidence within the screened population of more than 30%. Results of the two procedures were concordant in 42 of 43 cases with blunt cervical vascular injuries.

The remaining patients had normal CTAs confirmed by a normal CA, the investigators wrote.

The overall incidence of carotid artery injury (CAI) was 0.6% and vertebral artery injury (VAI) was 96%. Of the VAIs, 96% were associated with at least one cervical spine fracture. In the patients who underwent both CTA and CA, the detection sensitivity of CTA was 100% for CAI and 96% for VAI.

The overall sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of CTA for blunt cervical vascular injury were 97.1%, 100%, 100%, 98.9%, and 99.3%, respectively, they said.

An additional enhancement of

ferred by CTA is the ability to subtract other anatomic structures and focus on the vascular system exclusively, Dr. Eastman said. Vertebral artery injuries also are impressive when viewed at the CT workstation, he added.

When patients with negative CTA who did not have an angiogram were followed up at 3-12 months, none were found to have



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DR. BIFFEL

an injury or neurologic sequelae.

Following Dr. Eastman's presentation, discussant David A. Spain, M.D., agreed that 16-slice CTA is ready for prime time. However, "Is it ready for non-prime time?" asked Dr. Spain, who is with the Stanford University Medical Center, Stanford, Calif. "Who reads these studies at 2 a.m.? Three-dimensional reconstructions are very important to accurate interpretations, and if no one is available to read the exam, how long before you have a definitive answer as to whether these patients have an injury?" he added.

"I think obviously there's going to be some house staff reading at first," replied Dr. Eastman. "We're lucky at our institution that our neuroradiologists are exquisitely helpful ... so you get a reading almost immediately."

CTA vs. ART

The second study, conducted at Rhode Island Hospital and Brown Medical School in Providence, compared 16-slice CTA with 4-vessel cerebral arteriography (ART) in screening for blunt cerebrovascular injuries.

Screening detects many asymptomatic cerebrovascular injuries. "However, it has not been proven to prevent strokes, and thus many centers have been reluctant to implement screening protocols," they wrote. "It is particularly difficult to justify because ART, the gold-standard diagnostic test, is invasive and resource intensive."

"We developed our screening protocol using arteriography for symptomatic patients because ... we need a gold standard test when a patient is having symptoms or signs consistent with an injury," said lead author Walter L. Biffel, M.D. The investigators settled on 16-slice CTA for patients with high-risk mechanisms and injury patterns. To further capture any group that may be at risk, they enlarged the study group to include any patient with cranial or cervical trauma who was undergoing a CT scan.

The protocol called for CTA in all trauma patients with cranial or cervical trauma undergoing CT scanning. Any abnormality was further investigated with ART, and patients were followed for neurologic changes. The investigators reviewed records to determine if clinical injuries were missed by CTA, and then compared ART and CTA images.

Between June 2004 and February 2005, the team did 225 CTAs. A total of 17 patients (7.5%) were diagnosed with blunt cerebrovascular injuries, including 11 carotid and 6 vertebral injuries. CTA did not miss any clinically important blunt cerebrovascular injury, the researchers said.

"Importantly, nobody during the study period who had had a normal CTA developed signs or symptoms of a vascular injury, and that was what we set out to explore," Dr. Biffel said. "The disconcerting thing in this study is that two patients who didn't meet the screening criteria presented with symptoms related to a vascular injury."

One of those patients was an elderly man who had been in a minor auto accident. He was evaluated and sent home from the emergency department, but returned with persistent headache and Horner Syndrome. He was found to have dissection of the carotid artery. The other patient was a young woman who had fractures of the femur and clavicle who, because she didn't have cranial or cervical trauma, didn't undergo a CTA. She woke up the next day in the orthopedic service with a stroke.

"We've concluded from this study that CTA is a reliable, non-invasive screening test for clinically significant blunt cervical vascular injuries," Dr. Biffel said. "We need multicenter prospective trials to clarify the risk factors and to assess the accuracy of noninvasive screening tests and to evaluate the efficacy of treatment strategies," he added. ■