

Contemporary Medicine

CARDIOLOGY

Jefferson Hospital Testing Procedure to Prevent Stroke Recurrence

Study Could Yield Data Linking Stroke in Patients Aged 20 to 55 to Opening Between Atria of Heart

The Cardiac Catheterization Laboratory at Thomas Jefferson University Hospital has begun testing the safety and effectiveness of a minimally invasive procedure to seal a flap that can be present between the two upper chambers of the heart known as a Patent Foramen Ovale (PFO). The procedure could prove helpful in preventing recurrence of stroke in certain patients between the ages of 20 and 55.

"The cause of stroke in patients between 20 and 55 years of age is often difficult to determine," says Carissa C. Pineda, MD, a Clinical Instructor in the Department of Neurology at Jefferson Medical College and Thomas Jefferson University Hospital in the Division of Cerebrovascular Disease and Neurological Critical Care. "Many of these patients do not exhibit any of the traditional causes, such as diabetes, hypertension and high cholesterol that are common in elderly patients. Over the past several years, however, we have noticed an inordinate incidence of PFOs among younger patients we have treated for stroke. This indicates that there is an association between PFO and strokes."

Conduit for Blood Clots to Enter Brain

In some of those cases, where no other cause can be found, the PFO has been a conduit for small blood clots traveling up the legs through the veins, across the PFO and into the brain. Barring other, unforeseen causes, these traveling clots may be the source of stroke, adds Michael P. Savage, MD, Director of the Cardiac Catheterization Laboratory in the Division of Cardiology at Thomas Jefferson University Hospital.

"Over the past decade, clinicians have collectively amassed substantial anecdotal evidence suggesting that, in many cases, the cause of these otherwise unexplainable strokes may be a PFO. In about 75 percent of all people, this PFO closes spontaneously within the first few days after birth. In the other 25 percent, however, the PFO remains open, providing an unobstructed pathway for clots to travel from the right side of the heart to the left side and to the brain, possibly causing a stroke."

Until now, neurologists and cardiologists have treated young and middle-aged patients with strokes in one of two ways: sealing the PFO with open-heart surgery, or prescription blood-thinners such as warfarin, the generic version of the popular anti-

coagulant Coumadin, to prevent clotting. Neither treatment is ideal, Dr. Pineda says. "Open-heart surgery is complex and risky," she notes. "And long-term use of blood thinners poses a risk of bleeding and greatly restricts activity, which is asking a lot of younger patients – especially those who are athletically inclined."

"The Next-Generation Therapy"

Those reservations have led to the initiation of what Dr. Savage calls "the next-generation therapy: a catheterization procedure that can be completed within one to two hours and requires the patient to spend only one night in the hospital." Dr. Savage and his colleague, David L. Fischman, MD, Co-Director of the Cardiac Catheterization Laboratory at Jefferson University Hospital and a staff member of the Jefferson Heart Institute, both perform this procedure. Through an incision in the patient's right or left femoral vein, which is located in the groin, and continuing to the PFO flap, Dr. Fischman or Dr. Savage threads a sheath (similar to an IV catheter, only much larger) that houses a small device called a PFO Occluder. The device is designed, manufactured and marketed by Cardia Inc. of Burnsville, Minnesota.

"The PFO Occluder looks like a two-sided umbrella," Dr. Savage explains. "Once we cross the PFO via the catheter, we open up that 'umbrella' on its left side and pull it against the opening, or septum, on the left side of the PFO. Then, we release the umbrella on the right side. The Occluder then ends up closing like a clamshell, thereby obliterating the hole between the two sides."

Still, there is controversy regarding the treatment of PFOs. There are devices that have been approved by the U.S. Food and Drug Administration for certain "humanitarian" use exception for some patients who have had recurrent strokes and for whom blood thinners lend little relief. "The general consensus is that these individuals should have the opening closed before another stroke occurs," Dr. Savage notes. Yet, he says, there is the danger that such devices may be overused. Physicians may use the device for patients who have had only one stroke in order to prevent another.

Dr. Savage and Dr. Pineda hope that, following a year of follow-up with each patient, the national study in



Michael P. Savage, MD



Carissa C. Pineda, MD

which they are slated to participate will have supplied enough data not only to vindicate the procedure but also to formalize the conclusion that a PFO is a treatable cause of stroke in younger patients.

"Hopefully, the study will demonstrate conclusively that insertion of the PFO Occluder will decrease patients' risk of having another, recurrent stroke in the future. It should also encourage doctors to search more actively for PFOs when examining patients with stroke," Dr. Pineda concludes.

For more information, please contact Kathleen Keefe McAllister, RN, BSN, Clinical Research Coordinator, Jefferson Heart Institute, at 215-955-9725, kathleen.keefe-mcallister@mail.tju.edu, or call 1-800-JEFF-NOW.

Part of National Trial

The Cardiac Catheterization Laboratory currently is treating patients referred by neurologists on staff at the Acute Stroke Center at Jefferson. These neurologists include Dr. Pineda, Director Rodney D. Bell, MD, who is also Professor of Neurology at Jefferson Medical College, and David G. Brock, MD, Assistant Professor of Neurology at Jefferson Medical College and Medical Director of the Neurosensory Program/Neuro-Intensive Care Unit.

These patients constitute the first, "roll-out" phase of the study to test the safety and efficacy of this procedure. It will be followed by a randomized trial later this summer, during which some patients will be treated with insertion of the Cardia PFO Occluder, others with Coumadin. The trial may provide sufficient evidence to prove conclusively that there is a link between PFO and stroke.

Jefferson is one of about 50 medical centers in the United States that will participate in this study, which altogether will compare the long-term results for 150 patients treated with the Occluder against 150 treated with Coumadin.



Cardiologist guides sheath, containing Occluder, across PFO flap into left atrium...



...opens up Occluder "umbrella" on its left side...



...then pulls Occluder against left-side of flap and releases right-side umbrella to seal hole entirely.



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