Adelson leading trial examining hypothermia as therapy for brain swelling in TBI

by Marc Lukasiak
Children's Hospital of Pittsburgh

Department vice chairman for research and director of the Pediatric Neurotrauma Center at Children Hospital of Pittsburgh’s, P. David Adelson, MD, will lead a $11.5 million National Institutes of Health-funded clinical trial examining the effectiveness of induced hypothermia as a therapy for brain swelling in children who have suffered traumatic brain injuries.

Dr. Adelson, the A. Leland Albright Professor of Neurosurgery at the University of Pittsburgh School of Medicine, will lead researchers from 12 sites throughout the country in this trial—the third phase of this extensive study.

Researchers plan to enroll 340 children up to age 16 in the five-year, randomized trial, which is being funded by the National Institute of Neurological Disorders and Stroke. In Pittsburgh, Children’s will serve as the clinical site for the study and the University of Pittsburgh will serve as the coordinating site.

A previous Phase II clinical trial of induced hypothermia therapy led by Dr. Adelson at Children’s found that moderate hypothermia therapy is safe and may potentially improve outcome. Results of that study were published in the journal Neurosurgery in April 2005.

“We’ve proven this therapy is safe. Now if we can determine that it is effective, it would be a major breakthrough because currently there are very limited treatments that improve outcome following traumatic brain injury in children,” Dr. Adelson said.

“The belief is that cooling impacts the cascade of events that leads to brain swelling. Reducing brain swelling potentially could prevent further injury.”

Patients in the study selected to receive hypothermia therapy will be cooled to between 32–33 degrees Celsius (89–90 degrees Fahrenheit), using special cooling blankets and/or cooled saline injected intravenously. They will be cooled for 48 hours and then followed by researchers for one year to track outcomes, with a battery of tests being conducted at six and 12 months following injury.

The specific aim of the study is to determine if surface-induced moderate hypothermia (33°C for 48 hours) reached within four hours after severe brain injury improves outcome with low toxicity in patients with low admission temperatures (< 35.0°C).

The study has added a secondary hypothesis that patients who reach 35 degrees within two hours of injury will have improved outcomes compared to those who reach 35 degrees later than two hours.

According to federal law and University of Pittsburgh policy, those who participate in a clinical research study must provide, or in the case of a child, have a guardian provide informed consent. Because of the nature of this trial and the fact that hypothermia must be induced within six hours of injury, it may be impossible to obtain consent at the time of brain injury. For this reason, researchers are notifying the public that informed consent will be waived. Researchers will make every attempt to contact family members to provide notification and obtain consent for continued participation as soon as possible.

Patients may enter the study in one of two ways;

1) randomization in the field by EMS personnel in helicopters staffed by personnel trained by study centers,

2) randomization upon arrival to the emergency department of the study hospital within two hours of injury.

Currently at UPMC enrollment occurs in the emergency department. Pending completion of community consultation and IRB approval enrollment will begin thru EMS system utilizing STAT Medevac helicopters serving the counties of Armstrong, Butler, Westmoreland and Mahoning Co. Ohio.

Some of the other major centers participating in the trial are: University of California, Davis Medical Center (University of California Davis); Miami Children’s Hospital and Jackson Memorial Hospital (University of Miami); Children’s Medical Center of Dallas (University of Texas Southwestern Medical Center); Penn State Milton S. Hershey Medical Center (Penn State University); Johns Hopkins University Hospital, Duke University, Long Island University, Semmes Murphy Clinic (University of Tennessee), and Harborview Medical Center (University of Washington).
Hypothermia study demonstrates pediatric leadership

The pediatric neurosurgery program at the University of Pittsburgh continues to be one of the crowning jewels of the Department of Neurological Surgery’s clinical and academic effort. This service provides care for the majority of children in Western Pennsylvania as well as many in West Virginia, Ohio, and New York due to its advanced capabilities, geographic proximity, and because it has remained open to all forms of insurance assuring that no child can be denied access to its facilities.

One of the primary focuses of our pediatric neurosurgery effort over the past decade has been the academic study and clinical management of head injury, which is nationally responsible for approximately 100,000 pediatric hospitalizations per year. This work is especially important in view of research that now shows that Kennard’s principle of neuroplasticity may not translate into children recovering more successfully than adults from head trauma.

Despite prior beliefs, these victims may in fact have worse outcomes than adults suffering equal force injuries. Because young patients often do not have prior formal documentation of IQ and other cognitive functions it can be difficult to determine the performance toll taken by a head injury. Pediatric frontal lobe damage may also not manifest itself until later in life when deficits in executive functions and the effects of disinhibition make work and play in a less structured environment difficult. While many children with closed head injury do go on to perform well in school and demonstrate no changes in IQ, studies have shown that many have overall poorer vocational outcomes compared to their non-injured counterparts. Hence, while pediatric head injury is a problem of youth it may take until adulthood to make a final determination as to its effect on the individual and society.

Since his arrival in Pittsburgh over 10 years ago David Adelson, MD, has focused his academic efforts on improving patient outcomes following pediatric head injury. Having already shown in an NIH funded multi-center study that hypothermia can be safely carried out in children, he now moves on to demonstrate whether or not this treatment can reduce brain swelling and, as a result, improve outcomes following head trauma. It is with great pleasure, therefore, that we are able to announce and describe in this newsletter Dr. Adelson’s leading of an $11.5 million 12 site National Institute of Health funded clinical trial studying the effectiveness of induced hypothermia as a therapy for brain swelling in children suffering from traumatic brain injury.

Dr. Adelson’s work has proven to be a regional and national resource that will hopefully shed light on the processes involved in pediatric head trauma and the means available to ameliorate the secondary and controllable events that follow the initial injury. We look forward to reporting the results of this study in the years to come. In the interim, if you know of any children that may benefit from early intervention following injury please feel free to notify our center. With your help, neurosurgeons at the University of Pittsburgh’s Children’s Hospital hope to improve pediatric outcomes which will translate into more productive adults and a more functional society.

Amin Kassam, MD
Chairman
Department of Neurological Surgery
PMC Presbyterian has just opened a new operating room suite for image-guided brain and spine surgery. The suite is a fusion of high resolution computed tomography imaging (using a GE 64 slice CT scanner) with the latest advances in neuroendoscopic equipment provided by Storz, Inc. and image guided software provided by Stryker, Inc. and Elekta, Inc.

Patients undergo their brain or spine procedure in the scanner itself or in specially integrated OR beds after completion of the imaging component of the procedure.

The suite optimizes space by inverting the scanner position from its usual place in a diagnostic CT scanner suite. The patient’s head or body is advanced through the scanner aperture and the surgical team sits at the head of the patient.

During selected procedures intraoperative imaging can be performed. Immediately after the therapeutic component of the procedure, a post intervention scan can be done to assess the result and exclude potential complications.

In addition to procedures designed to facilitate resection of a lesion or mass, this dedicated surgical site is used for stereotactic (guided) brain surgery, spinal surgery, and even for chest surgery procedures performed by colleagues in the thoracic surgery division.

The room is linked to online image retrieval systems as well as data linked to MRI scanners in the hospital.

Patients can have fusion of their intraoperative scans with other preoperative imaging such as MRI, PET scans, and magnetoencephalography (MEG) imaging. An entire intraoperative head MRI can be performed in less than four seconds using high resolution narrow slice views of the head, and then reformatted in multiple planes.

Using multiple flat screen high definition monitors, the surgeon can see the preoperative and intraoperative imaging, plus endoscopic or microscopic views, and ongoing anesthesia monitoring. Both general and sedation anesthesia cases are possible.

The first image integrated operating room was opened at UPMC Presbyterian in 1982. A therapeutic GE 8800 CT scanner helped to revolutionize guided brain surgery by combining the surgical and imaging sites at the same place. This scanner was updated to a 9800 scanner 10 years later. More than 3000 surgical procedures were performed during the next 25 years.

Construction of the new operating room required integration of multiple new technologies. The operating room is an example of commitment to increasing the range and safety of minimally invasive brain and spine surgery.*
Earlier this year, Michael Horowitz, MD, chief of neurosurgery and director of the Center for Endovascular and Exovascular Therapy at UPMC Presbyterian, helped lead a team of surgeons and radiologists at University Medical Center at Princeton, NJ, successfully treat an impoverished Ecuadoran national diagnosed with a complex neuro-radiology procedure and unable to receive care in his homeland.

William Morocho Japa, 26, of Cuenca, Ecuador, was diagnosed with an intracranial aneurysm—a bulging, weakened wall of an artery that supplies blood to the brain. Although a common ailment, it can be life-threatening and doctors in Ecuador lacked the technology and expertise to treat it.

The Journey

Japa’s ordeal began in October 2006 as the result of a serious motor vehicle accident. After spending 11 days in a coma, he awoke in a hospital bed lucky to be alive. He remained hospitalized for three months. After surgery in Ecuador, physicians discovered the intracranial aneurysm during Japa’s medical evaluation.

Speaking through an interpreter, Japa said, “The doctors told me there was nothing they could do. I was going to be sent home to wait and see what would happen. I became very depressed; I felt hopeless.”

Word of Japa’s potentially life-threatening condition soon spread. Relatives and the Latino community in Hightstown, NJ, learned of it and began a dedicated effort to bring him there for treatment.

Father Miguel Valle, parochial vicar at Saint Anthony of Padua Catholic Church in Hightstown, suggested to Japa’s father-in-law Jose Sergio Naulaguari, that the family get in touch with fellow parishioner David Abalos, PhD. Dr. Abalos called Robbi Alexander, RN, program coordinator of Princeton HealthCare’s Community Education and Outreach Program who in turn contacted Barry S. Rabner, president and CEO of Princeton HealthCare. Rabner took an immediate interest in Japa’s case.

A team of Princeton HealthCare physicians was assembled to help treat Japa, including neurosurgeon Mark R. McLaughlin, MD—a graduate of the University of Pittsburgh neurological surgery residency program—internalist Victor D. Iturbides, MD and Donald F. Denny, MD, chief of radiology at Princeton HealthCare.

Princeton HealthCare and members of Japa’s medical team agreed to waive all costs related to Japa’s care and he was subsequently granted a medical visa to travel to Princeton. By the time he arrived in New Jersey, his aneurysm had doubled in size.

The Treatment

There are two main concerns related to an intracranial aneurysm. First, as an aneurysm gets bigger it places pressure on the nerves around the eye muscles causing eye movement abnormalities, double vision, headache, and facial numbness. This was the case with Japa who experienced all of these symptoms prior to the procedure. The main concern, however, was that the aneurysm could rupture resulting in vision loss or stroke, leading to severe disability.

An endovascular embolization was needed to treat Japa. Due to the complicated nature of this procedure, Dr. McLaughlin enlisted the help of Dr. Horowitz, a longtime friend, mentor and colleague and a world-renown expert in the procedure.

“An endovascular embolization is a minimally invasive catheter-based procedure designed to essentially patch the aneurysm, blocking it off from regular blood flow so it is no longer a problem.” Dr. McLaughlin said in explaining the operation.

“During the procedure, a stunt and coil device is positioned within the aneurysm blocking blood flow and preventing rupture. The platinum coil resembles a miniature slinky that when deployed, is designed to curl around inside of the aneurysm filling and stabilizing it. The material is flexible enough to fit and fill any aneurysm shape. The end result restores normal circulatory patterns alleviating symptoms and risk.”

The neuroradiology procedure used catheters that were guided with real-time X-ray technology, called fluoroscopic imaging. This allowed physicians to see and navigate Japa’s vascular system and treat the aneurysm from inside the actual blood vessel. The procedure took approximately 1.5 hours and physicians knew immediately afterward that it was a success.

According to Dr. McLaughlin, “The procedure was a complete success. By treating William’s aneurysm in this manner we have eliminated all risk of disability that he faced had this not been treated.”

“It was a pleasure helping my colleagues in treating William,” Dr. Horowitz said. “What they’ve managed to do in getting this young man here for treatment is nothing short of extraordinary. It’s a privilege to have been a part of it.”

In addition to services donated by the medical center and medical staff, several medical device companies—including Boston Scientific, ev3, Inc, Cook Medical, Cordis Corporation and Terumo Cardiovascular Systems—donated equipment and technology to Japa’s cause.

Appreciation

Speaking on the treatment that he received, Japa—a devout Catholic—said, “When I learned that there were people, some who are complete strangers, trying to get me to New Jersey for treatment I was completely overwhelmed. I felt incomparable happiness. There are no words to express my gratitude.”

(see Hope on page 6)
Patrick Reilly never saw it coming. This 46 year old man experienced the worst headache of his life in April of 2006. Emergency evaluation at UPMC Presbyterian revealed a subarachnoid hemorrhage (SAH). The most common non-traumatic cause of this type of intra-cranial bleeding is a ruptured aneurysm.

Digital subtraction angiography (DSA), which is available within 30 minutes at any time at PUH, is considered the gold standard for evaluating the blood vessels of the brain. This study revealed a 17x13 mm right middle cerebral artery (MCA) bifurcation aneurysm.

Michael Horowitz, MD, a neurosurgeon with fellowship training in interventional neuroradiology who has treated over 1,000 intracranial aneurysms, was able to discuss treatment options from the prospective of both specialties. While recent studies have shown the safety, and in certain circumstances, superiority of endovascular embolization of aneurysms, Dr. Horowitz felt the aneurysm would be best treated by an open approach involving removing the bone of the skull in order to place a titanium clip across the neck of the aneurysm. Amin Kassam, MD, the newly-appointed chairman of the Department of Neurosurgery and head of the exovascular surgery program at UPMC Presbyterian, agreed. This team has been working together since 1999 and has a combined experience of treating over 1,500 aneurysms.

The complexity of the aneurysm required multiple titanium clips and necessitated leaving a small residual to keep the main arteries open. The surgery was considered successful, allowing Mr. Reilly to leave the hospital neurologically intact.

Unfortunately, four months later Mr. Reilly returned with a new hemorrhage. Dr. Horowitz again performed DSA. After a quick conference between the endovascular and exovascular teams, the patient was taken back to the operating room for placement of another clip. The surgery went well, once again allowing Mr. Reilly to return home.

However, within less than a month, the patient presented with another hemorrhage. Repeat DSA revealed new growth of the residual aneurysm that was now amenable to endovascular treatment. Dr. Horowitz and his team of endovascular neurosurgeons and neurologists used a flexible catheter to maneuver nine platinum coils into the 5 mm residual aneurysm. Specialized Neuroform stents were also utilized to brace the coils in place and prevent herniation into the parent artery. The procedure went smoothly and Mr. Reilly once again made it home from the hospital neurologically normal.

It has now been over eight months since Mr. Reilly’s journey began. What he didn’t expect before, has become a constant reminder of life’s brevity. Fortunately, a recent DSA showed complete embolization of the aneurysm with no new growth.

The treatment of such complex lesions requires the dedicated and specialized attention of neurosurgeons with the training and experience to handle the problems and complications that often arise. At UPMC Presbyterian, Drs. Horowitz and Kassam continue to provide urgent eagerly await the next 1000 aneurysms.

Multispecialty approach provides edge in subarachnoid hemorrhage case

by Brian Jankowitz, MD
PGY-5 resident

Top left image reveals a large right middle cerebral artery aneurysm as defined by digital subtraction angiography. Top middle image further delineates the morphology of the aneurysm by utilizing the latest angiography innovations. The aneurysm is digitally reconstructed in 3D after obtaining a biplanar arteriogram. The remaining pictures show complete embolization of the aneurysm after endovascular placement of nine platinum coils.
SPORT trial results favor lumbar herniated disc surgery
(continued from back page)

were more likely to have more significant pain or a neurological deficit than the patients in the randomized clinical trial group. Interestingly, 22% of patients who entered into this group because they did not want to be randomized to having surgery because they wanted to try nonsurgical therapies first ultimately underwent a discectomy during the two year follow-up.

In this study, there was a statistically significant difference in all primary and secondary outcomes, favoring surgery. “In this nonrandomized evaluation of patients with persistent scatica from lumbar disk herniation who had operative or usual care, both treatment groups improved considerably over two years...patients who underwent discectomy had significantly better self-reported outcomes than those who had usual care.”

The SPORT Trial was the largest, best designed, most costly, and most important clinical trial ever performed to study a spinal disorder and its surgical management. This information will be of great benefit to our patients who suffer from scatica. We can now inform them with the highest level of scientific evidence possible that lumbar discectomy surgery is safe, it is not necessary with patients with mild symptoms, and it is highly effective for patients with severe symptoms. In the near future, we will have available to us the results of the trial that evaluated the surgical treatment of lumbar stenosis and degenerative spondylolisthesis.

Hope for Ecuadoran
(continued from page 4)

He added, “I am indebted to University Medical Center at Princeton, University of Pittsburgh Medical Center, and Drs. Horowitz, Denny, and McLaughlin for taking care of me and to Mr. Rabner.

Although Japa’s family in Ecuador was not able to travel with him, he spoke with his wife, Francisca Naulaguary Panjon, 26, and daughter, Diana Morocho Japa, 3, every other day. I can’t wait to return to my wife and family; I miss them so much. That’s what I am looking forward to the most, seeing my wife and daughter. I have faith that God will get me there.”

Recent donations Department of Neurological Surgery

(All amounts ‘Up to $1,000, except where noted.)

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Lunsford Named Distinguished Professor

University of Pittsburgh Chancellor Mark A. Nordenberg named L. Dade Lunsford, MD, Distinguished Professor of Neurological Surgery at the University of Pittsburgh. The title constitutes the highest honor the university can accord a faculty member as it marks extraordinary, internationally-recognized scholarly attainment. Previous surgeons given the honor of distinguished service and distinguished professor include Bernard Fisher, Richard Simmons, Thomas Starzl and Eugene Myers.

Graduation Dinner Honors Chief Residents

A special black-tie graduation reception and dinner was held June 22 at the Pittsburgh Field Club honoring chief residents Pedro Aguilar, MD, Joseph Ong, MD, and Michael Sharts, MD, on their successful completion of the University of Pittsburgh’s seven-year neurological surgery residency program. The event was attended by faculty members, colleagues, family and friends.

Dr. Aguilar is remaining at the University of Pittsburgh Department of Neurological Surgery as an assistant professor specializing in spine surgery and pain management. Dr. Ong is joining Neurosurgery at the Beach in Virginia Beach, Virginia, while Dr. Sharts is joining Eastern Neurosurgical and Spine Associates in Greenville, North Carolina.

Annual Resident Teaching Awards

Dr. Sharts was named best resident teacher as chosen by the department staff; Amin Kassam, MD, was chosen as best faculty teacher as chosen by the residents.

UPMC Again Ranked Among Best

The University of Pittsburgh Medical Center has once again received national recognition for its clinical programs, ranking among the top hospitals in the nation in U.S. News & World Report magazine’s annual “America’s Best Hospitals” survey. The 2007 results—published in the July 23 edition of the magazine—also mark UPMC’s eighth appearance on the magazine’s prestigious ‘Honor Roll’ list, which includes only 18 of over 5,000 hospitals surveyed nationwide and demonstrates “marked breadth of expertise,” according to the magazine.

Research Grant Awards

• “Molecular Prognostic Markers for Low-Grade Gliomas.”
  Ian Pollack, MD, Brain Tumor Society, $199,946.

Media

• P. David Adelson, MD, was featured in a national Associated Press article May 21 discussing the technological advancements and improved results in surgical treatment of epilepsy. The article was carried in numerous newspapers and magazines across the country including the Pittsburgh Post-Gazette, New York Times, Cleveland Plain Dealer, Miami Herald, San Francisco Chronicle and Forbes magazine. The report was also picked up by a number of internet news organizations including ABCNews.com, CBSNews.com, MSNBBC.com and FOXNews.com.

• Dr. Kassam, and Carl Snyderman, MD, were featured in a live webcast on or-live.com June 14 discussing the safety and effectiveness of the endoscopic endonasal approach (EEA) brain surgery in pediatric cases.

• Drs. Kassam and Snyderman, were featured in a WQED-TV (Pittsburgh) OnQ news magazine show April 9 chronicling the use of endonasal neurosurgery in the care of a brain tumor patient.

Prominent Lectures

• Peter Gerszten, MD, was a visiting professor at the University of California at San Francisco, May 30 - June 2.

• Dr. Kassam was a visiting professor at Massachusetts General Hospital/Harvard on April 12. He was also the Penfield Lecturer at the Annual Congress of Canadian Neurological Sciences Foundation in Edmonton, Canada on June 21. Dr. Kassam also taught courses on cadaveric dissection at the Cirugia Endoscopica Transnasal De La Base Del Craneo in Madrid, Spain, July 2-3, and at the International Workshop on Advanced Transnasal Endoscopic Skull Base Surgery in Barcelona, Spain, July 5-6.

Congratulations

• Douglas Kondziolka, MD, received the 2007 Jacob Fabricant Award from the International Stereotactic Radiosurgery Society at the organization’s biannual meeting in San Francisco in June. The award is given to the individual or individuals establishing longstanding and significant contributions in the field of radiosurgery

• Kelly Powell, Center for Image-Guided Neurosurgery clinical secretary, was selected as UPMC “Patient Ambassador of the Month” for February.

• Debra McHugh, medical secretary for Dr. Kassam, was awarded the UPMC “You Are A Star Award” for the fourth quarter of the ‘07 fiscal year.

Welcome

• Theresa Gombos, RN, nurse coordinator for Dr. Okonkwo; Ali Raja, MD, clinical instructor, pediatric neurosurgery; Donna Englert, clinical secretary for Dr. Gerszten; Gina Brophley, physician assistant; Peggy Zaborowski, MINC clinical secretary; Julie Martin, MINC clinical secretary.

Personal Congratulations

• Dr. Sharts married Michelle Kraus on April 28; Ricky Madhok, MD, and wife (Naveena) had a baby girl (Liya Shann) born on June 12; Joseph Ong, MD, and wife (Sheila) had a baby boy (Virgil James) born on July 14.

Upcoming Events

• September 10-12: Gamma Knife Radiosurgery Training for Nurses. Three-day basic training course for nurses and other allied health care personnel interested in providing clinical care for patients undergoing Gamma Knife radiosurgery. (412) 647-7744.

• September 11: Visiting Professor. Paolo Cappabianca, MD, Professor and Chairman of Neurological Surgery, Università degli Studi di Napoli Federico II, Naples, Italy.

• September 6-8 and 23-25: Minimally Invasive Endoscopic Surgery of the Cranial Base and Pituitary Fossa Course. Presentation of minimally invasive techniques for endoscopic surgery of the cranial base and pituitary fossa. (412) 647-6358.

• September 24-28: Principles and Practice of Gamma Knife Radiosurgery. For neurosurgeons, radiation oncologists, medical physicists and other physicians interested in Gamma Knife treatment certification. (412) 647-7744.
SPORT trial shows safety, efficacy of surgery for lumbar herniated disc disease

by Peter C. Gerszten, MD, MPH, FACS
Associate Professor of Neurological Surgery

Dave S. Atteberry, MD
Chief Resident

Eighty percent of individuals will have at least one episode of low back pain in their lifetimes. Lower extremity radicular pain, or sciatica, lasting at least two weeks occurs in almost 2% of the adult population each year. Back problems are the fifth leading cause of medical visits in the United States and the leading cause of work-related disability. However, ninety percent of patients with back pain recover without any intervention within four weeks.

Lumbar discectomy surgery is the most common surgical procedure performed for back and leg symptoms in the United States, but the efficacy of the procedure relative to nonoperative care has remained unknown. The National Institutes of Health therefore initiated a trial in March 2000 called the Spine Patient Outcomes Research Trial (SPORT) at 13 centers throughout the United States in order to compare outcomes after two years of surgical versus nonoperative treatment for patients suffering from lumbar disc herniation. Throughout this trial, we served as the sole neurosurgeons on the Data Safety and Monitoring Board which oversaw this study.

Five hundred patients with pain caused by a herniated disc for at least six weeks were enrolled in this trial and randomized to either surgery or nonsurgical therapy. An additional 743 patients, who declined to be randomized for the trial, were enrolled in an observational cohort investigation and followed for two years as well. The results of both of these studies were recently published in the Journal of the American Medical Association (JAMA 296(20):2441, 2007).

In the randomized clinical trial, the results favored the group which underwent surgery at all follow-up time points. The study concluded, “Between-group differences in outcomes were consistently in favor of surgery for all outcomes and at all time periods.” In addition, the rate of complications in the surgical group was exceedingly low. Significant controversy has surrounded this study because of the “intention-to-treat” analysis that decreased the true positive effect that surgery had on outcome. Furthermore, there was a significant degree of crossover of patients in both arms with 40% of patients assigned to surgery not getting surgery and 45% of patients assigned to nonsurgery ultimately undergoing discectomy. In the “as-treated” statistical analysis, the results even more heavily favored surgery.

In the observational cohort portion of the study, patients who declined to be randomized were followed and allowed to choose between surgery and non-surgical therapies. The patients in this group overall

(see SPORT on page 6)