Endovascular Today: How would you describe the current status of stroke treatment?

Dr. Broderick: We are close to the 10-year anniversary of the first proven treatment for acute ischemic stroke—tissue plasminogen activator (tPA)—and throughout the past 10 years, there has been a lot of evolution in the field in terms of acceptance for reperfusion therapy. We have learned that tPA is effective when given very early; the sooner, the better.

Is there a population of patients who respond to reperfusion therapy beyond 3 hours, or who do not qualify for thrombolytic therapy? I think the PROACT 2 study demonstrated the effectiveness and feasibility of opening arteries beyond 3 hours after onset. In this study, the intra-arterial (IA) approach included only a thrombolytic agent—prourokinase. It showed that an IA approach using a thrombolytic agent is effective.

One of the big developments during the last 5 years is using imaging as a way of identifying patients beyond the early time window who still have salvageable brain. I think the studies that have the most data behind this approach are the desmoteplase studies, in which patients were selected for inclusion by MR imaging and were randomized to intravenous (IV) desmoteplase or placebo. There is preliminarily...
These treatments continue to be studied, and new treatments for the 3- to 6-hour group—IA prourokinase—most physicians’ minds, a proven, but not FDA approved, one promising and FDA approved treatment for the greater-group tPA—for those patients in the 0- to 3-hour group. We have treatment, I believe that we are in an exciting time. We have yet to demonstrate in a randomized trial whether using the device to open the arteries beyond 3 hours improves patients’ outcomes as compared to standard care, which currently includes no IV or IA approaches to recanalization beyond 3 hours after stroke onset.

Another big development throughout the last few years is the concept of combination therapy, in which a proven treatment, IV tPA, is initiated as quickly as possible—to get the low-hanging fruit, as I like to say—followed by an IA method of recanalization by additional medication or use of a device to accelerate clot removal, such as the Concentric system or the Ekos Microlysus catheter (EKOS Corporation, Bothell, WA). We are trying to determine if the IV plus IA approach is superior to IV alone and if reperfusion beyond 3 hours with mechanical devices or other means not only opens arteries better but also makes a difference for patients from an outcomes standpoint. Answers to those two questions will come from randomized trials. There is also a host of different mechanical approaches currently in pilot testing or on the drawing board that may be added to the armamentarium but face the same questions and challenges after they receive approval.

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—Dr. Duckwiler

Dr. Duckwiler: In the global perspective on acute stroke treatment, I believe that we are in an exciting time. We have one scientifically proven and FDA-approved treatment—IV tPA—for those patients in the 0- to 3-hour group. We have one promising and FDA approved treatment for the greater-than 3-hour group—the Merci device. We also have, in most physicians’ minds, a proven, but not FDA approved, treatment for the 3- to 6-hour group—IA prourokinase. These treatments continue to be studied, and new treatment strategies, drugs, and devices are in trials. Moreover, progress in the organization of stroke centers and networks, education of emergency personnel, diversion programs to designated stroke centers, and patient education are all helping to get acute stroke care to where it needs to be.

There needs to be more effort in several areas, but it is heartening that tremendous progress is being made; the number of patients being treated for acute stroke is steadily increasing.

Dr. Hopkins: We are looking at many different approaches. I think that the real message is that this is an iterative process. We try different things; some work, some do not. It is very disappointing that most of the neuroprotective agents have not panned out. The most exciting one on the horizon is cooling. I do not know where that will go, but we are starting to cool some patients; this will need to undergo trials. However, if we could extend the treatment window by rapidly cooling the patients and then using mechanical clot removal to open the vessels, we can certainly hope to see improved long-term results. It is disappointing that, when you look at the data and the trials evaluating IV tPA, you find that, at 3 months out, still nearly 60% of patients who were treated with IV tPA are either dead or disabled.

We still have a long way to go in terms of successful treatment of acute stroke. We see an ever-increasing number of strokes as the population ages. By 2014, we will be seeing 750,000 to 800,000 strokes per year. There is a crying need for more and better ways to open the vessels. In our own shop, we have had an evolution to a more mechanical and a less lytic approach, markedly reducing the incidences of hemorrhages that we have seen. We find that the Merci Retrieval device works in approximately 50% to 60% of the cases, and some of the newer designs that Concentric Medical has introduced now seem to be a bit more effective. The major problem with the Merci Retrieval device is that once a clot forms in the middle cerebral artery around an embolus, it becomes adherent to the vessel, and the device sometimes bounces off the clot without capturing it.

We have been struck by the fact that stent placement, when all else fails, seems to have a very positive effect on opening the vessel. At the 2006 American Heart Association Scientific Sessions, we recently reported on a number of patients who were treated with stents when everything else failed. The downside to that report is that these patients were fairly far out on the timeline because we had tried everything else before stent placement. Those 20 patients showed that when all else failed, we could still open the occluded vessels with a stent, causing the average NIH Stroke Scale to move from approximately 18 to 6 in the group of survivors. The downside is that we lost six of those patients, and they were the sicker patients. We learned that...
younger age and lower NIH Stroke Scale were positive predictors, and T occlusion was a bad sign. Time to revascularization was significant as well. We eventually applied to the FDA and just received approval for a single-center IDE to begin a stent for stroke trial, an early-phase trial looking at stenting as a way of opening the artery.

I am convinced that the more tools we have available, the better our chances are to open the artery and achieve return of function. That brings us back to the question of when to actually try to open a vessel. We are increasingly relying on CT perfusion and discovering that blood volume is a key driver for indicating a patient in whom opening the vessel would be helpful. If we find that the brain appears to be compromised and there appears to be dead brain with markedly decreased volume and basically a black hole on the CT perfusion, we usually do not recommend any intervention at all. If CT perfusion indicates that we have a significant amount of viable, but poorly perfused, brain, with no large area of decreased blood volume (ie, no black hole), then we are aggressive in opening up the vessels, no matter how much time has elapsed from onset. Using this algorithm, we have been more successful in attaining good outcomes, particularly in younger patients with middle cerebral artery lesions as opposed to T (ICA terminus) lesions. We believe that there is a great opportunity to treat patients who were previously not salvageable by discerning the patients who have viable brain and intervening regardless of the timeline. Now, we have improved techniques to open the vessels and a better handle on selecting treatable patients. Once we sort this out, it may be time to start a randomized trial.

It is pretty fantastic to see patients who come in with high NIH stroke scores in whom the brain appears to be salvageable, and you open the vessels. One of the most dramatic things I have ever seen in medicine is to watch a patient who presents with a bad stroke, who is basically hemiplegic and aphasic, start moving and talking on the angio table as the vessel opens up. It is like throwing a switch in a significant number of these patients; the clinical results are quite dramatic.

Dr. Guterman: The past decade of acute stroke care has achieved numerous milestones, as well as helped to define what needs to be done in the future. We have seen that IV thrombolytic therapy with tPA is effective if administered within 3 hours. We learned that effective blood pressure management in the peri-infusion period is critical to prevent intracranial hemorrhage. Although early stroke trials relied on CT as the primary imaging modality, we learned that standard CT imaging alone is inadequate. It is clear that MRI provides the most specific and sensitive method for evaluating acute ischemic infarcts. In addition, MR perfusion can identify cerebral tissue at risk. Unfortunately, this technique is motion sensitive and has limited utility. In our stroke centers, CT perfusion has enabled a fast and easy method for evaluating ischemic brain and helped to differentiate between infarcted brain and salvageable brain. This ability has helped to define the patients who are most appropriate for revascularization and helped to decrease the intracranial hemorrhage risk associated with revascularization.

Although numerous stroke registries and trials have been completed, few have provided evidence to cause major shifts in practice. The Merci trial, a nonrandomized registry, demonstrated that at least 50% of patients who present with acute stroke symptoms within 8 hours of onset can be revascularized using a clot retrieval device rather than lytic agents. These data tend to support better outcomes in patients who are successfully revascularized, yet not all revascularized patients have good outcomes.

When standard techniques of lysis and clot retrieval fail, intracranial angioplasty has proven clinically useful, yet no trial has been proposed. Intracranial stent techniques have been reported useful in vessel salvage procedures and may have an increasing role in the future.

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Dr. Murphy: Stroke therapy is centralized in hospitals that have large infrastructures that can supply this 24 hours a day, unless there are pioneers, such as Bruce McIff, MD, or Carl Black, MD, in Utah, who are really willing to put the time and energy into creating a stroke program. They take great personal responsibility and drive the program themselves. One of the biggest weaknesses in current stroke therapy is that the neurologists are not interested in treating stroke. They are interested in motion disorders, such as Parkinson’s disease or epilepsy, but they are not interested in the poorly reimbursed interruption of their regular day by an acute stroke patient that takes them out of their clinic; in fact, our financial systems of the neurology business do not support stroke care. That is one fundamental problem.

There is also a generational change occurring in neurology, but in fact, interventional neuroradiologists are more frequently found than stroke neurologists. That needs to be said bluntly. At the same time, on the interventional neuroradiology side, there is a focus on devices as a solution. If we keep focusing only on industry-developed devices that are
pushed by interventional neuroradiologists with consulting agreements from those companies, we wind up with devices that are not usable by the average image-guided therapist in the community. You have to be pretty good to put a Concentric Merci Retriever device in the middle cerebral artery. Those skills are not readily available.

Stroke is a problem across the entire world. We need to make it simple. We need to have appropriate levels of stroke intervention for each individual hospital setting, depending on the level of service available in that hospital.

The other thing we need to do is to open up stroke intervention to anyone who can place the catheter safely in the internal carotid artery or the vertebral artery. The patients do not care who treats them; they only care that that person is well trained. If we do that, although it is disruptive to the business plan of radiology, it means that other fields can get involved. We need to create sustainable teams of technologists, nurses, and physicians to treat this so that people are not on call every single night of their lives. We need to look at the things that interrupt the smooth movement of the patient through the health care system. We have to overcome our tribalism and make sure that we deliver the level of care needed by the patient. We have to look for conflicts of interest on the industry side and make sure that they are fully disclosed in all the papers that are written because that is currently not happening. We need to be certain that we have science to back up what we do.

Endovascular Today: Is it too early to say what the implications of current stroke data are? Are there obstacles to randomized data in the area of stroke?

Dr. Murphy: The fundamental problem is that we do not have enough patients. How do you randomize patients when they are acutely ill? From whom do you get consent? How do you get IRB approval for this? We have more studies than we have patients at Johns Hopkins; we have to fight over who gets randomized into what because we have so many studies. In fact, none of the neuroprotective agent studies worked. We spent millions of NIH and industry dollars on these studies, and none of them have worked. What brains like is blood, but we continue to do drug studies—people are looking for the ‘Holy Grail’ answer.

The closest thing to the Holy Grail that we have is cooling. That work is done outside the US because people cannot get through the FDA and cannot get funding for clinical research in this country. You can get funded if you are going to terrorize rats for years, but try and get funded for a clinical study from the NIH—you may as well go to the moon. If you look at the good clinical work that has been done, it is outside the US; it is done in Canada, Europe, and Australia.

The best study on cooling was actually the simplest study; it was done in Melbourne, Australia, on sudden cardiac death. It was extremely simple; they carried bags of ice in the ambulance. The problem with that is you cannot sell bags of ice as an industry device; there is no business plan, so nobody is going to do that in the US. There is no future trying to sell bags of ice to an ambulance. In Melbourne, they put bags of frozen saline on the patient and cooled them in the field. They brought the temperature down immediately. The sooner you introduce hypothermia to the patient, the better. The American solution is to come up with these wild catheters that you put into the inferior vena cava or blankets you put on the patient, but they do not work as well as simple bags of ice placed on the patient in the field. It takes 20 minutes before the ambulance reaches the hospital where the patient can get the catheter or the blanket and be cooled. If you chill them in the field, they do well. You can prolong that intervention with cooling and do the catheter-based intervention.

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Dr. Broderick: I think the biggest obstacle to randomized data is people thinking they know the answer to whether patient outcome has improved before knowing that is actually the case. An open vessel is not always a good thing. It is all about reopening a vessel in the appropriate patient at the right time. You must document whether recanalization does indeed improve patient outcome. I worry about people thinking that mechanical reperfusion works in all time windows in all arteries, even if you have some data from imaging that suggests salvageable brain. That is something we do not know the answer to yet.

Another obstacle associated with mechanical reperfusion is the new financial incentives for physicians and hospitals to treat patients with acute stroke before we know whether such therapy improves patient outcomes. Such financial incentives encourage treatment of patients with acute stroke outside of trials. This potential danger has been seen in other areas (eg, the spine) in which there are many different techniques that are used—none of which have been shown to improve patient outcomes in randomized trials as compared to standard surgical techniques. A lot of hardware is placed in the spine because these procedures have associated financial incentives. I think that financial incentives are an important potential obstacle to randomized trials and something we have to be aware of in the field. We
have to look at the data carefully before we advocate a given therapy as benefiting patients.

**Dr. Hopkins:** I think it is a very difficult issue because when you actually see what happens when you open a vessel, you think, “How can I not offer this treatment?” But Dr. Broderick is right; we do not have enough data to know for sure. However, to some extent, we need to learn from historical data. We have a good handle on what the outcomes will be with the currently approved therapy, and maybe we can figure out ways to use that historical data to judge what we are doing until we absolutely must have randomized trials comparing mechanical opening to medical or IV therapy. These are tough questions, and I do not yet know the answer.

**Dr. Guterman:** Dr. Hopkins and I participated in phase 1 of the PROACT trial, which required that a placebo be infused intra-arterially as a control for prourokinase. Given the technical progress that has been made in cerebral vessel recanalization in the last decade, it is difficult to deny patients the latest methods in vessel recanalization so that they can be entered into a control arm of a clinical trial that may deny them treatment. In the past, stroke trials have required very specific inclusion criteria. Randomized prospective stroke trials are difficult to implement and expensive to support. Yet, the stroke neurology community has questioned the registry data. Endovascular treatment of acute stroke is experiencing a rapid growth in technology. As a result, clinical trials with a device may be in the early enrollment phase as new devices become available. As a result, practice patterns evolve that are not driven by randomized controlled studies.

**Dr. Broderick:** It was noted in the Concentric trial that the interventionists employed other tools to open the artery beyond the Merci Retriever. The problem is the more things we use to reopen the artery, the more we get complications. It is not just about opening the arteries. Sometimes trying to open arteries leads to bad outcomes. I have seen patients who had their arteries opened, even within the first 5 hours, who experienced no positive change, or worsened. You see people who bleed—after you open their artery—not necessarily because of the lytic drugs but because we opened up the artery into a damaged brain or damaged blood vessel.

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We have an emotional need, when we see sick patients, to try to help in any way we can, and yet we have to step back and approach it scientifically. If we have a good therapy, we must test it and make sure it is really benefiting the patient. The value of randomized trials is to see whether something really improves outcomes. Cardiologists, in general, have been good about pursuing randomized trials. They may not do it initially, but they always come to the point where they see whether something really has improved outcomes.

**Dr. Guterman:** I agree with Dr. Broderick, but in patients with severe dominant hemisphere strokes, we know their outcome is overwhelmingly poor if left untreated. If they present after 3 hours of symptom onset, our only alternative is to use whatever tools are available to help recanalize the occluded vessel. I feel that perfusion imaging helps select the subpopulation of patients who potentially can benefit most.

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—Dr. Broderick

**Dr. Hopkins:** The changing technology is one of the reasons why, in the ongoing NINDS-funded IMS III trial, we specifically built change into our trial’s design. If something surfaces that clearly advances recanalization, does well in pilot testing, and receives FDA approval, and we deem it clearly better than our current device, then we have a way to include that new device in our trial. The idea is we are talking about a strategy, not a given tool. I like to make the analogy that when a plumber comes to fix your pipes, he does not bring just one tool; he brings a whole toolbox. The key is to have tools in your toolbox that every interventionist with sufficient device experience can use. That is the way
you can do randomized trials with strategies rather than testing a special device. I believe it will be hard to do a randomized trial with just one given device, rather than a whole approach. No two lesions are the same; no two vascular systems are as easy to navigate. The combined IV/interventional approach that we are testing in IMS III will open the arteries better than IV alone, and we hope this will also improve patient outcomes.

Dr. Hopkins: We hope that now that one mechanical device has been approved, the pathway to market will not be as tedious for the next devices. If we have a good pathway to market and the FDA is allowing more admission, we will have some new devices, such as the Penumbra device (Penumbra, Inc., San Leandro, CA), without too much delay, and that will really help things.

Dr. Duckwiler: I think the IV tPA data are very strong. The SITS-MOST registry in Europe has presented results very similar to the NINDS trial in the US that led to the approval of IV tPA. With this additional confirmation of the utility of this therapy, we hope that we can expand the ability of our healthcare system to deliver this essential treatment to more patients.

I believe that the IA prourokinase data are also very strong. However, because of costs of that study and the regulatory statutes surrounding drug therapy, it is not FDA approved. This remains a hurdle, but on the basis of that study, many interventionists are providing this care to patients.

Mechanical thrombectomy using the Merci device is FDA approved for use in acute stroke. However, as Dr. Broderick has pointed out, this approval was based on its ability to reopen vessels with a minimum of complications. It was not a randomized study designed to compare outcomes in control (untreated) patients. The studies—Merci and now MultiMerci—have shown that recanalization can be achieved with a minimum of complications in approximately 60% to 70% of patients. In patients who had success versus those who did not, the functional outcomes were better, and the mortality rate was lower. This has convinced many interventionists to provide this therapy when IV tPA cannot be given. But, belief is not proof, and eventually I think that a pivotal trial will be done.

I do take issue with the implication that there is a financial incentive to perform mechanical thrombectomy over a randomized trial. In my experience, all decisions to perform this therapy are shared decisions between the interventionist, stroke neurologist, and patient and/or patient’s family. Although it is true that there is a DRG payment to the hospital specifically for this therapy, I have never heard from or seen an administrator involved in this process, nor should they be. From the physician side, acute stroke therapy is a burden on one’s schedule. It seems to me that these cases always seem to occur late at night. Although there is some payment above the typical charge for a cerebral angiography, that is minor, and certainly the decision to perform this therapy is based more on our fundamental desire to help the patient suffering from an acute stroke.

Endovascular Today: What are the current trends in stroke treatment?

Dr. Duckwiler: The areas that seem to be moving fastest are organization of acute stroke care, networks and stroke centers, and interventional therapies. Also, using advanced imaging to select patients is becoming standard. This is part of the trend to try and identify the patients most likely to benefit from our advanced therapies.

Dr. Murphy: The current trends are built around the business plans of American medicine. You make a device, you patent it, you get FDA approval, and a large corporation buys your device. That is not in the best interest of the patient. We need simple solutions. Simplicity is cheap, but cheap, unfortunately, does not sell. There is a profound flaw in how we do things. It is the simple solutions that are dif-

Dr. Broderick: Neuroprotection is still a good concept, but we have yet to find an approach that works to this point in randomized trials. The primary trend, just like in acute myocardial infarction, is to reopen the artery in any way possible. Some people are testing ultrasound intracranially and extracranially to try to accelerate the effects of drugs. Some are trying other medications rather than tPA, and we have already discussed the burgeoning use of mechanical devices. Opening up arteries in sufficient time and protecting the brain until that occurs are the two fundamental approaches to treating acute ischemic stroke.

There are other types of stroke—hemorrhagic strokes—that are treated differently and for which a number of new approaches are being tested. In ischemic stroke treatment, you are trying to open the artery; in hemorrhagic stroke treatment, you are trying to stop the bleeding, such as by using hemostatic agents during the first several hours and dampening the effects of blood where it should not be. The neurosurgeons are trying to tackle those situations with some innovative surgical approaches as well.
Dr. Hopkins: I agree completely.

Dr. Guterman: So far, we have not been able to find the right drug to protect the brain. Most neuroprotectants have worked well in rats but not in humans. All the cooling trials, external or internal, have not provided any compelling evidence to drive adoption of cooling techniques. Yet, cooling and pharmacologic methods of cerebral protection seem to make sense. To date, lytic agents and clot-retrieval devices remain the only demonstrated methods to open cerebral blood vessels and impart some improved outcome on those patients in whom we get the vessels open.

The trend for some members in the interventional community is to use whatever tools are available to open the vessel quickly and safely. Yet, centers with this capability are limited in number.

Endovascular Today: Would any interventionist debate that the use of neuroprotection in acute stroke is essential?

Dr. Hopkins: Yes, I would think that everyone agrees that neuroprotection is a key issue, but the concern is trying to find neuroprotective agents that actually work. We really have not had much success at that.

Dr. Broderick: Clearly, we know that in the setting of cardiac arrest—a complete loss of blood flow to the brain—if you restart the heart and you reperfuse a globally ischemic brain in the setting of very early hypothermia, the outcome is better. This is a fundamental proof that rapid hypothermia can be effective in acute ischemic brain. What we do not know is if hypothermia can work in focal brain ischemia and in what time period.

Dr. Hopkins: The trials that have looked at cooling patients who have occluded vessels for aneurysm surgery have produced encouraging data. We temporarily cool the patient, clip the vessels, and then rewarm the patient. We have a fair amount of data to suggest that cooling patients in the situation in which you purposefully occlude a vessel for a significant amount of time does provide some protection. Although the scenarios are different because the cooling is performed beforehand, it is encouraging that data suggest this works during surgery and may be helpful during stroke.

Dr. Duckwiler: Time remains our enemy. Anything that can increase the viability of the brain until an appropriate therapy can be instituted would be of invaluable help. Also, limiting any damaging cascade of events associated with the acute brain injury would be of tremendous help in all cases. Proving therapies in this area has been problematic, but ultra early administration of neuroprotection strategies is only now being studied.

Dr. Murphy: Show me a study that even works. Brains like blood—it is that simple.

Endovascular Today: What are the future directions of stroke treatment?

Dr. Duckwiler: I believe that an integrated system of acute stroke management is just around the corner. We have talked about and we are working on individual blocks in that system. IV tPA, mechanical techniques, and neuroprotection all address some of the components of care. Paramedic involvement, rapid triage and diversion, and care protocols are other components. I agree with Dr. Broderick’s statement about the toolbox. The care pathway from patient/bystander recognition of an acute stroke to post-rehabilitation home care and secondary stroke prevention measures are an assembly line on which we apply these tools. Care pathways are always critical to the best outcomes, and I believe that one big future direction is to look at our care in a more global view.

Dr. Broderick: Neuroprotection will still be an important goal. There is even a very interesting approach under testing where infrared laser energy is administered through the skull in patients with ischemic stroke. We will see what happens when we get to a larger phase 3 trial, but neuroprotection and reperfusion will continue to evolve in the next few years. To me, the fundamental question is whether we can show that a reperfusion strategy that includes intervention is superior compared to IV medication alone—that will be the study that changes the field. Interestingly, the Europeans are also assembling a study to look at the interventional approach versus IV tPA alone.

Technology will continue to evolve quickly; we have to monitor it closely. We have a limited number of interventional physicians, but we must be sure that whoever is in the field is extremely well-trained in the performance of interventional procedures in the cerebrovascular tree,
understands the brain and how it works, and knows how to care for brain problems. Treating acute stroke patients is not just about opening an occluded proximal carotid artery with a stent, such as patients with symptomatic carotid stenosis, but also about having the expertise to open other more distal arteries in the brain and to care for the patient with significant brain problems before and after the intervention. Neurologic critical care may improve the outcome as much as opening the artery. Somehow, we have to get more people involved who have this capability.

Dr. Murphy: I believe in the simple application of hypothermia, but I am not impressed by the outcomes of albumen therapy. In fact, some of them have been a disaster. However, CoAxia, Inc. (Minneapolis, MN) has a balloon device for the abdominal aorta that is simple, useful, and under development, and I believe any skilled physician can place this device.

I think we need to create tiered approaches for each hospital. We have been very successful, for example, at building a network around central retinal artery occlusion. We have treated 44 patients with acute monocular blindness with excellent results. In the prospective study, 21 people were treated with IA tPA into their ophthalmic artery, and the remainder were treated conventionally. Seventy percent of those treated conventionally (no tPA) went blind in that eye. Seventy percent of those treated with tPA had restoration of vision. We had a 14-hour time window. This treatment worked very effectively and helped us build a network.

Another issue here is building successful, strategic partnerships and networks at multiple institutions to ensure that service is available and that competitive institutions collaborate to provide care on a 24/7 basis. We must ensure that sustainable teams are made possible at each institution, that there are multicare on-call stroke teams in the cities, and that these networks are built on a shared system where there is no leader, there are codirectors, and people meet and are able to do everything for the patient. The system should not be based on financial incentives. This scenario would be the biggest breakthrough—more than any device.

Dr. Guterman: I feel that hypothermia could have a role if we could cool in a fast and efficient manner and then reopen the occluded vessels. I am not sure that cooling alone will prove useful as a stand-alone therapy.

PhotoThera (Carlsbad, CA), a new company, employs externally applied infrared energy to the brain as a means of providing free electrons to mitochondria in the ischemic brain in the region of the acute stroke. They are presently in clinical trials.

Endovascular Today: Are there differences in the way stroke is treated in Europe versus the US?

Dr. Broderick: I think that a clear convergence has taken place in the last 10 years. tPA has been approved for use in Europe, although another trial was required to explore a time window beyond 3 hours (ECASS III). In addition, the Europeans have been very involved in the use of imaging, and many places have become more active in neurointervention. There are a lot of similarities. There is a focus on neurocritical care in Europe, as well. Although there is some variability in stroke care among countries in Europe, there is also variability in areas of the US. One of the nice developments is that we have been able to collaborate with our colleagues in Europe and Asia, where tremendous progress is also being made. Asia certainly has a large number of stroke patients, and I suspect that as we move ahead in the next 10 years, we will see more and more centers from the Asian continent become leaders in recruitment into randomized acute stroke trials.

Dr. Murphy: There is a greater acceptance of old age in Europe than there is in the US. One issue I would like to discuss is the stupidity of not approving the use of the Wingspan (Boston Scientific Corporation, Natick, MA) stent for CMS patients. I had an 80-year-old patient undergoing multiple surgeries and embolizations, which are all approved and reimbursable although he has no future and no life expectancy. If I were to treat the same aged patient with an intracranial stenosis, who is completely salvageable, I would not be able to treat him because CMS does not cover it and my hospital would not allow it.

CMS has done a wonderful job of protecting their patients, from non–science-based care in carotid stenting and preventing disease is other areas. In this case, they are wrong. They need to take a look at that and see that we can use the Wingspan stent in CMS patients who have failed medical therapy. My administrators at Hopkins are not allowing me to treat CMS patients without demanding those people guarantee to pay enormous bills before the procedure. This is a disgrace.

Dr. Duckwiler: Europe is a big and diverse place, and the current management of acute stroke is highly variable. However, because of differences in the regulatory pathways, and with excellent and forward-looking practitioners, some technologies can and are being tried in Europe first. But the most important thing is that throughout the world, there is recognition that there are things we can do about acute stroke, there is a tremendous unmet need, and there is only going to be more need in the future. I am personally excited to be in this field at this time, being part of a sea of change in the management of this deadly disease.