3. Create multiple on-line presences to be able to reach all individuals interested in our teachings. Establish virtual discussion groups. Remember that adequate size assures focus (but bigger is not always better). Open-source Websites and transmission of knowledge, even through miniblogs (such as Twitter), podcasts, and video on demand, should all allow us to reach our audiences 24/7.
4. Build a digital archive of our teachings. I have started posting all of our Division's scientific exhibits on our blogsite.
5. Use virtual environments to promote educational programs (for an example of virtual campuses see: http://secondlifegrid.net, accessed July 8, 2009). The buzzwords in this environment are "immersion," "visualization," and "collaboration."

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M. Castillo
Editor-in-Chief

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EDITORIAL

Trials and Tribulations

"Do you want to spend the rest of your life selling sugared water or do you want a chance to change the world?"

Steve Jobs

Interventional neuroradiology has reached such a level of maturity that several prospective randomized controlled trials (RCTs) of its treatment offerings are now being completed. This is an important milestone because these trials represent the highest level of evidence to support a medical practice, but these landmark trial results are not always being greeted kindly. Like teenagers transitioning into adulthood, we are sometimes resistant to maturation. Some have gone so far as to question whether or not randomized prospective clinical trials are necessary in our field. We delude ourselves if any of us really think that special rules apply to our field that would make RCTs impractical or unnecessary. We cannot continue to practice on the basis of anecdote and uncontrolled case series. This unscientific practice often leads us along in a blissful ignorance, in which we offer relatively unproven therapies to patients who are looking to us for real improvements in their conditions. We need to recognize that if we are going to change the world through the practice of our specialty, we need to become legitimately scientific.

Although the neurointerventional field is mature enough that RCTs can now be completed, there are still cultural issues within our specialty that inhibit the conduct of RCTs. For instance, there is no shortage of large egos and strong opinions in the neurointerventional field. We often accept opinion as fact, especially if it is our own opinion. There is also a tendency in our field to follow the practices of charismatic "thought leaders" like lemmings. There is occasionally not so much thought behind what a "thought leader" is doing, so sometimes they might be better described as "do leaders." We each need to differentiate what we think from what we know. No matter how positive we might feel about the safety and efficacy of treatments that we offer, we need to recognize that reasonable people both inside and outside of our field are justifiably skeptical. While it is true that no one needs a randomized trial of the efficacy of a parachute, we should not presume that all of our treatments are at the parachute's level of obvious efficacy.

If a trial is conducted to study a procedure that you believe is efficacious, you should be supportive. If you turn out to be correct and your preferred treatment is indeed efficacious, the study will support your practice. If your predictions about the results turn out to be incorrect, then you should be grateful that the trial helps you see your error and you should consider altering your practice. There may occasionally be trials for which you would not be ethically comfortable enrolling patients. However, you should be cautious in questioning the motives of those who do participate in a trial in which you yourself would not participate. None of us have a monopoly on truth or ethics. If someone is skeptical about the value of one treatment versus another, the most ethical thing for that person to do may be a trial. There are historical examples of treatments that many physicians were convinced were efficacious but, when tested scientifically, proved to be nonefficacious (eg, extracranial-intracranial bypass).

Some neurointerventionalists struggle ethically with the concept of randomization. Many are so accustomed to thinking that they can recommend a best therapy for a patient that they start to question their own ethics if they consider subjecting a patient to randomization. Moreover, they are so accustomed to giving patients confident recommendations about therapy that they have no idea how to have a conversation with a patient about clinical equipoise between 2 therapies and the necessity of RCTs to advance medicine. As I have gained experience with such discussions of clinical equipoise with patients during the years, I have come to believe that enrollment failures much more often result from physicians who are uncomfortable and ineffective in conducting this conversation, than from patients who are unreceptive or incapable of understanding.

We may find fault with various details in RCT design. It is easy to nitpick about the details of an RCT. It is important to realize that principal investigators must spend enormous amounts of time thinking about innumerable details and must make tough decisions to keep the trial moving forward. As participants, the rest of us need to accept such decisions and move on as well. If you strongly disagree with the goals or design of a trial, then you should certainly not participate. However, you should also avoid questioning the motives or intelligence of the organizers of the trial. It is generally true that no one cares more about getting a valid result from a trial

or understands the topic of study better than the principal investigator. The principal investigators who lead these trials commit to an enormous amount of work. We need to help them move our field forward. This will mean putting aside our personal agendas and participating in something bigger than ourselves. As we progress in this regard, a cadre of committed active enrolling centers must develop. The centers that actively participate in RCTs will be an essential part of the future of neurointerventions, while those that do not will struggle to have relevance.

Credible complaints could certainly be made that some RCTs, such as the recent trials of carotid stent placement versus carotid endarterectomy, were seriously flawed with regard to methodology, but it is too late now. These trials have completed enrollment, and the results are being published in major journals. Physicians who refer us patients and individuals who make decisions about health care expenditures are going to see these publications and undoubtedly be influenced. Our response now should not be to disparage clinical trials in general, because that is unrealistic and will not achieve anything positive. If we do not think that a good RCT was performed, we have to look to ourselves and ask why. Why did we not provide better leadership? Why did we not perform our own study? Maybe there are compelling and justifiable cultural and political excuses for our lack of input into these trials, but we should look for ways to avoid our inadequate participation in the future.

No single RCT should ever mark the end of research into treatment options for a particular disease. Good clinical trials typically generate ideas for future trials. For example, if an RCT demonstrates a lack of efficacy of a specific treatment in a broad population, that does not exclude the possibility that specific subgroups of patients may benefit from that treatment. Similarly, if an RCT does demonstrate efficacy of a specific treatment in a broad population, that does not exclude the possibility that specific subgroups of patients may be harmed by the treatment. There are always refinements to be made. Also, the field changes with time, which leads to new questions to be addressed by RCTs. If we did the trials of carotid endarterectomy of the early 1990s again and gave patients aggressive modern risk-factor management, the results might be quite different today.

RCTs are indeed imperfect. This should not be surprising because the people who run them and the patients enrolled in them are imperfect. Our inexperience and naiveté have slowed many neurointerventionalists in the past with regard to initiating clinical trials. Issues like changing technology and details of trial design tend to lead us to a "paralysis of analysis." We cannot let our lack of perfect solutions deter us from moving forward with an RCT. Indeed, it is only through an RCT that we will arrive incrementally at better solutions.

We all learned in medical school that RCTs were the best form of medical evidence, and nothing has changed since then in this regard. What has changed is that neurointerventional RCTs are now actually being completed. RCTs are the "currency of the realm" in evidence-based medicine, and it will likely become increasingly hard for us to thrive economically without this currency. A few in our field are resisting the power of RCTs, but resistance is futile. There is no question that RCTs of the procedures that we offer will continue to be conducted, and there is no question that the results of these trials will have a profound impact on our practice. The only question is which neurointerventionalists will be leading these studies and which will be led by them.

H. Cloft
Senior Editor

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