ERCUTANEOUS ENDOVASCULAR PROCEDURES CONFER benefits to patients similar to those seen with minimally invasive surgery, such as minimal invasion of the body cavity, reduced pain, shortened recovery time, and more rapid return to work. However, minimally invasive surgery and endovascular procedures also share similar problems.\textsuperscript{1} As with minimally invasive surgery, endovascular procedures require physicians to perform invasive procedures guided by 2-dimensional video images while using and manipulating tools with limited degrees of freedom. Endovascular procedures also require the operator to adapt to significantly decreased tactile sensation and overcome similar proprioceptive-visual conflict issues from manipulating long wires or instruments that can fulcrum against the body wall. These hurdles combine to create substantial challenges for physicians training to acquire these skills.

The challenge of training physicians for performance of endovascular procedures has been brought to the forefront because of the rapidly expanding application of carotid stenting for treatment of carotid artery stenosis into the broader medical marketplace. Currently, few physicians are experienced in the carotid stenting technique. However, with the recent US Food and Drug Administration (FDA) approval of carotid stents, many physicians from multiple specialties will want to learn the carotid stenting technique. Traditional training methods for new procedures include performing the procedure on animals, cadavers, or mechanical models or supervised performance of the procedure on patients. Inherent problems with these traditional training strategies include the ethical and anatomical problems of training on animals, risks posed with repeated exposure to radiation, and the expense of consuming real medical devices. However, the majority of procedural training in the United States still occurs on patients with direct mentoring by experienced physicians during an actual clinical procedure.

This tradition of training on patients has raised concern among the profession and the public about how physicians will acquire sufficient skill to safely perform new, potentially high-risk, endovascular procedures such as carotid stenting.\textsuperscript{2,3} Because the carotid arteries are the primary blood vessels to the brain, if an embolus of thrombotic plaque dislodges and enters the brain during a carotid stent procedure, the patient could have a stroke or die on the operating table. As with other procedures, carotid stenting has a definite learning curve.\textsuperscript{4} However, unlike many other procedures, the risk conferred to the patient in this procedure from the physicians’ learning curve is unacceptably high. Traditionally, it was assumed that if a physician performed a procedure a certain number of times or trained for a period of time then that physician became proficient in the procedure. However, essentially no mechanism for measuring posttraining skill has been used.

Both number of procedures and duration of training are, at best, crude surrogate measures of skill and fail to factor in the variability in individual rates of learning. This approach to training produces physicians with considerably variable skills that have been only subjectively assessed by those who trained them.\textsuperscript{5} This variation is particularly important with carotid stenting because this procedure crosses multiple clinical specialties with each bringing a different skill set to the training table. For example, a vascular surgeon has a thorough cognitive understanding of vascular anatomy and management of carotid disease but may lack some of the psychomotor technical skills of wire and catheter manipulation and may be unfamiliar with management of the fluoroscope. Conversely, an interventional cardiologist will have the technical skill with catheter-based...
procedures but may not be as familiar with the anatomical and clinical management issues. A sound training strategy must ensure that both of these specialists and others are able to meet an objectively assessable minimum level of proficiency in all facets of the procedure.

State-of-the-art training in many other high-skill professions, such as aviation, involves virtual reality simulation. First proposed as a method for surgical procedural skills training in 1991 by Satava,6 acceptance of this training approach has been slow partly because of skepticism within the medical community and the lack of well-controlled clinical trials to demonstrate its efficacy. Frequently referred to as virtual reality (VR) training for the operating room (OR), “VR to OR” is the benchmark study for any medical virtual reality simulator. In the last 2 years, 2 such studies have been reported using a prospective, randomized, double-blind design and have shown that residents who were trained using a low-fidelity virtual reality trainer made significantly fewer intraoperative errors than a standard-trained group during the performance of laparoscopic cholecystectomy.7,8 The first of the studies7 showed that virtual reality–trained residents made 6 times fewer intraoperative errors and performed the procedure 30% faster when dissecting the gallbladder from the liver bed. What both trials demonstrated is that a significant part of the learning curve can be acquired through virtual reality training outside the OR. While all of the trainees in these studies were residents, when their videorecorded operative performance was compared with that of experienced attending surgeons, the performance of the trained resident did not differ significantly from that of the attending physicians. That is, the residents had acquired technical skills through training on a virtual reality simulator that approximated those of experienced attending surgeon operators.

The fidelity of the virtual reality simulators available for training in carotid stenting is orders of magnitude superior to the virtual reality trainer used in these 2 studies.7,8 The endovascular virtual reality simulators produce a look and feel that closely approaches working on an actual patient.9 Endovascular virtual reality simulators produce a look and feel that closely approaches working on an actual patient.9 In addition, these simulators measure and record every catheter and wire movement and can distinguish correct from incorrect movement sequences. Therefore, for the first time in endovascular medicine this technology can be used to train and assess complex, minute wire and catheter skills. Furthermore, the trainee physician can receive objective feedback on his/her performance during and after completion of the simulated cases to enhance and speed learning.

Rather than relying on crude surrogate measures of skill such as number of procedures performed or duration of training, specific procedure performance skills can be taught and assessed objectively. Furthermore, a technical skills benchmark or proficiency level can be set based on the objectively assessed performance of experienced operators performing the same task, and trainees can be required to reach that proficiency level before they ever deploy a carotid stent in a patient.9 In fact, this training methodology is one of the primary reasons for the success of the “VR to OR” studies.7,8 This method ensures a much less variable skill set and removes subjectivity from the training process. This objective training and assessment strategy can also serve to eliminate arguments among specialties regarding training and credentialing. As long as a vascular surgeon, cardiologist, interventional radiologist, or neurosurgeon can demonstrate the desired proficiency level, he/she should be allowed to perform the procedure.

Medicine is currently undergoing a shift in the way procedural skills are taught. In March 2004 we met with the FDA at a closed-door meeting to inform officials of the evidence that currently exists demonstrating the power of virtual reality simulation for improved medical intraoperative skills training and objective skills assessment and how virtual reality simulation should be applied. At a public meeting in April 2004, an FDA panel voted to accept a proposal that virtual reality simulation would be an important component of a training package for carotid stenting.10 The company manufacturing the carotid stent system would work with physician trainers to educate physician trainees using a tiered training approach including online, multimedia components. Trainees would learn catheter and wire handling skills on a high-fidelity virtual reality simulator until the trainees achieved a level of proficiency in didactic and technical skills.

In August, the Society for Cardiovascular Angiography and Interventions, the Society for Vascular Medicine and Biology, and the Society for Vascular Surgery, representing the majority of physicians who will perform carotid stent procedures, publicly supported the use of virtual reality simulation for carotid stent training. They also included simulation as part of a joint competency statement.11 On September 1, the Centers for Medicare & Medicaid Services announced its intention to expand coverage of percutaneous transluminal angioplasty of the carotid artery with placement of an FDA-approved carotid stent and to permit coverage for participants in a large FDA-mandated postmarket approval study for the newly approved device.12

A carotid stenting trial, which began in fall 2004, will explicitly assess the efficacy of virtual reality simulation to train physicians to place a carotid stent.13 In this trial, physician trainees with no prior carotid stenting experience will be trained to an objectively established level of proficiency on a virtual reality simulator prior to performing stenting in a patient. In this study of training for a high-risk, high-profile procedure, the clinical outcomes of the patients of the virtual reality–trained physicians will be compared with a case-matched group of patients who had their carotid stent inserted by experienced operators as part of the trial responsible for FDA approval of the carotid stent. This is by far the largest and most important investigation of the role of virtual reality for procedural skills training ever conducted.
The skills required for the practice of modern procedure-based medicine are frequently so difficult to learn that traditional training is no longer acceptable, and learning on patients is increasingly suboptimal. Eleven years after Satava reported his vision of virtual reality for training procedural skills in minimally invasive surgery, this technology and proficiency-based training method are beginning to change the training paradigm in all of procedural-based medicine. Hereafter, physicians performing the procedure on patients for the first time will have a more homogeneous skill set, which will lead to safer, objectively assessed intraoperative performance. The ultimate goal is for this shift in procedural skills training to result in improved quality of care for patients.

REFERENCES

Lung Cancer Etiology
Independent and Joint Effects of Genetics, Tobacco, and Arsenic

Habibul Ahsan, MD, MMedSc
Duncan C. Thomas, PhD

Lung cancer is the number one neoplasm in the world, both in terms of incidence and mortality. The incidence of lung cancer differs by geographic area, sex, age, and over time, reflecting the effect of the underlying distribution and trend in use of its principal determinant, tobacco smoking. Although 80% to 90% of lung cancer cases occur in current or past tobacco smokers, only a small fraction of smokers (1%-1.5%) develop lung cancer, depending on how much and how long an individual has smoked and the presence of other causes of lung cancer. Clearly, because all lung cancers do not occur in smokers and the vast majority of smokers do not develop lung cancer, other etiological factors can independently (in the absence of smoking) or jointly (in conjunction with smoking) cause lung cancer, beyond the purely stochastic nature of the disease process. These factors include genetics (measured as family history), arsenic exposure, radiation exposure, and other environmental carcinogens. Although genetic factors probably contribute in all populations, the contribution of other factors is population-specific. See also pp 2977 and 2984.