

Keeping Up With Cardiovascular Therapies

Current applications and future directions of medical simulation in cardiovascular medicine.

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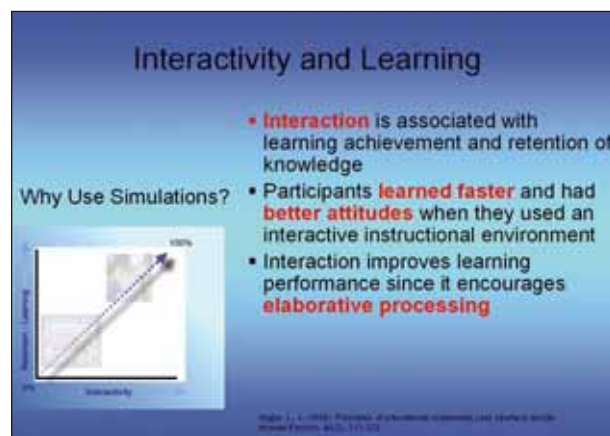
The field of interventional cardiovascular medicine is a dynamic, rapidly expanding discipline that demands technical excellence by its practitioners. There is an ever-increasing number of technologies being applied to different areas of the cardiovascular system. This rapid expansion of minimally invasive therapies requires the concomitant development of effective methods to educate physicians in optimal applications and techniques. To this end, we have established The Interventional Cardiovascular Training Center in Philadelphia to (1) train physician operators in new and emerging technologies, (2) partner with industry to develop, refine, and test new interventional tools, and (3) train nurses and technologists in optimal application of new cardiovascular procedures.

The Center has developed an integrated approach to education using the case method of teaching. Three types of educational tools are utilized in concert: medical simulation, live-case demonstrations, and focused state-of-the-science reviews related to specific clinical case scenarios. Educational formats include (1) small group (6 to 12 physician participants) programs dedicated to specific topics (eg, carotid stenting), (2) preceptorships in which individuals devote block time to master new techniques, (3) larger training courses involving 150 to 200 attendees, such as The first Fellows Global Interventional Cardiovascular program occurring in December 2005 in Philadelphia, cosponsored by the Society of Cardiovascular Angiography and Intervention, and (4) presentation at large interventional meetings (eg, TCT and Euro PCR).

ROLE OF SIMULATION

We have used a sophisticated medical simulation system as a key component in cardiovascular training. The simulator encourages the trainee to accelerate his or her learning

curve because interactivity is a hallmark of this educational technique. Interactivity is associated with a higher level of learning achievement and retention of knowledge (Figure 1).² Furthermore, interaction improves learning performance because it encourages elaborative processing of information. We have used the simulator as a substitute for live-case demonstrations in the following format: a complex case is presented by a "talking head" that appears on the screen and the history, physical examination and noninvasive data, and angiographic findings are presented. A featured guest operator (an acknowledged expert) is then invited to perform the procedure. The cases are written so that multiple branch points are encountered and choices are available to the operator, with different clinical consequences resulting from proper or incorrect choices. Large video screens showing the simulated cinefluoroscopic images, hemodynamics, and EKG displays are visible to the



audience. The moderators can interrupt the action at any branch point and query the attendees using an audience response system, encouraging maximum interactivity. A separate screen displays the scientific bases for various therapeutic strategies.

The operator must demonstrate requisite skills in interpreting clinical data and in performance of the procedure. The operator must select optimal angiographic views and interventional equipment, perform with technical dexterity, and utilize adjunctive pharmacology appropriately.

There are unique advantages of simulated live cases over the traditional live-case method. For example, complications can be programmed that require skilled operator response. These complications may be infrequently encountered in traditional live cases. The trainee can observe the reasoning of an acknowledged expert as he or she works through a difficult problem or serious adverse event; when a complication occurs in a "real" live case, the transmission is often switched (for understandable reasons) to a smoothly running case. A very large library of cases can be developed with specific teaching points for each case. Furthermore, cases that do not lend themselves to the traditional live-case format can be demonstrated. For example, acute myocardial infarction intervention is often excluded from traditional live-case demonstrations. We have utilized this method of teaching for complex coronary interventions, carotid stenting with distal neuroprotection, and interven-

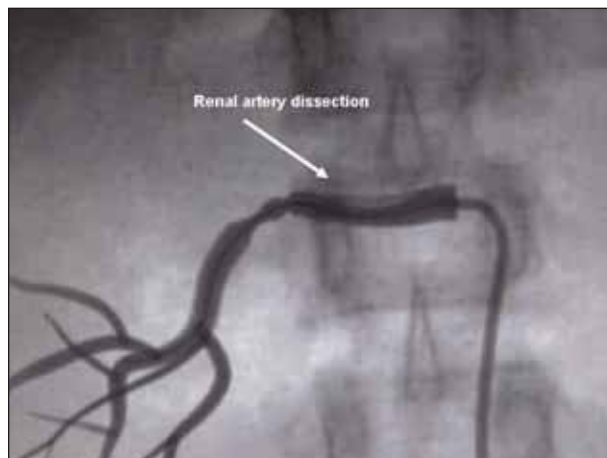


Figure 2. Complication occurring during simulated renal artery intervention. The ability to program a variety of adverse events such as this dissection enhances the ability to work through complications.

tional therapy for structural heart disease (Table 1).

We have also used the simulator as an individual training tool in which the trainee works through the clinical case scenario during a course. For example, during a program in carotid angiography and stenting, the trainee must first understand proper patient selection, interpret noninvasive testing, and perform four-vessel angiography correctly. Second, the operator must learn interventional equipment selection and proper use of embolic protection devices. The trainee should master techniques of dealing with different aortic arches and must deal with varying lesion complexities and understand the intricacies of adverse event management.

Because the simulator can track variables such as procedural complications, correct/incorrect selection of treatment strategies, and equipment and fluoroscopic time, a score can be generated that may be compared to a group of expert operators for that procedure. These data can be used to direct trainees toward areas of weakness and to improve their skills. Furthermore, the quantitative information generated during these exercises may be used in the future as a testing component during certification examinations and quality assurance initiatives.

CARDIOVASCULAR PROCEDURES IN WHICH SIMULATION WILL PLAY A MAJOR ROLE

Complex Coronary Artery Disease

With the advent of drug-eluting stents,² proper patient selection and advanced levels of technical expertise are increasingly important. Patient and lesion subsets, which were previously in the realm of the surgeon, are now being referred for percutaneous intervention. Safe performance of

TABLE 1. SIMULATED LIVE-CASE SESSIONS GIVEN AT TCT AND EUROPCR

Complex Coronary Intervention

- Saphenous vein graft intervention
- Acute myocardial infarction
- Unprotected left main
- Multivessel coronary intervention
- Calcified lesion

Carotid Stenting With Neuroprotection

- Carotid stenting in a patient with unstable angina and left main disease
- Carotid stenting in a patient with distal embolization requiring neurorescue
- Development of dissection of internal carotid artery after stent placement
- High-grade lesion of common carotid in a postradiation patient

Structural Heart Disease

- Closure of patent foramen ovale
- Closure of atrial septal defect
- Left atrial appendage exclusion

these procedures will require advanced simulation training in techniques such as left main stenting, bifurcation stenting, use of distal protection devices, and rotational atherectomy.

Peripheral Vascular, Renal, and Brachiocephalic Disease

As interventional cardiologists, vascular surgeons, and interventional radiologists move to perform peripheral interventions, simulation for aortoiliac, renal, and brachiocephalic disease should play an important role in training and certification for these indications (Figure 2).

Carotid Stenting With Neuroprotection

There are an estimated 250,000 patients in the US at risk for cerebrovascular accident due to carotid disease.³ Training for interventional cardiologists, radiologists, and vascular surgeons will be in great demand because recent data from randomized trials have shown a benefit from carotid stent placement compared with carotid endarterectomy.⁴ Stent manufacturers require completion of carotid simulation procedures as a prerequisite to approval for use of their products in patients. Medical Simulation Corporation (Englewood, CO) has developed a 2-day, small group (six physicians) carotid training program implementing live-case observation, didactic presentations and simulation, coauthored by Michael Jaff, DO, and Dan McCormick, MD. More than 170 physicians have attended the carotid simulation training courses at 15 leading medical centers across the US (Table 2), starting at Hahnemann University Hospital in Philadelphia in March 2004. There is also a need to incorporate new technologies into the armamentarium of operators performing these procedures. New filters, balloon occlusion devices, proximal protection systems, newer-generation stents, and delivery systems will need to be tested and taught on simulators (Figure 3).

ASD/PFO Closure

Atrial septal defects and patent foramen ovale are a class of atrial septal structural defects that may cause paradoxical embolism and heart failure. These defects, also previously in the purview of the cardiac surgeon, are increasingly being referred for percutaneous intervention.⁵ These techniques require a profound understanding of indication, three-dimensional structural heart anatomy, and interpretation

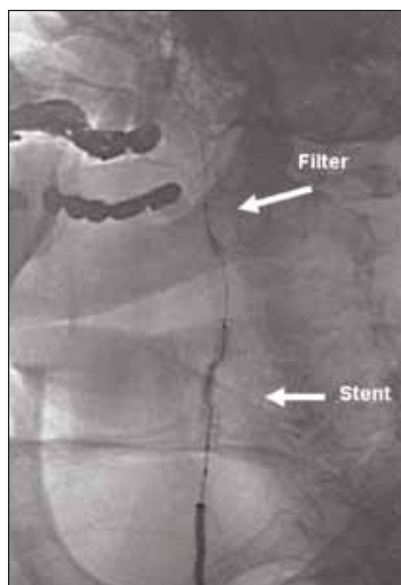


Figure 3. Carotid stent simulation. This emerging technique is utilizing simulation in a variety of training courses.

tation of online ultrasound images via transesophageal echocardiography and/or intracardiac echocardiography (Figure 4).

Furthermore, a plethora of new devices are being developed for closure of atrial and patent foramen ovale defects, each with specific technical steps. These steps can be mastered with simulation.

Transseptal Puncture

Long relegated to a role as minor niche diagnostic procedure, the importance of transseptal puncture has re-emerged with the advent of techniques such as left atrial appendage exclusion, biventricular pacing, and percutaneous mitral valvuloplasty. Simulation lends itself particularly well for training in these procedures.

Left Atrial Appendage Exclusion

The recognition that approximately 85% of thrombi that embolize as a result of atrial fibrillation originate from the left atrial appendage (LAA) has given impetus to the development of LAA exclusion.⁶ Given the frequent incidence of atrial fibrillation along with the complications associated with warfarin therapy, this technology may have an enormous impact in cardiovascular therapeutics. LAA exclusion is technically demanding, requiring training in transseptal

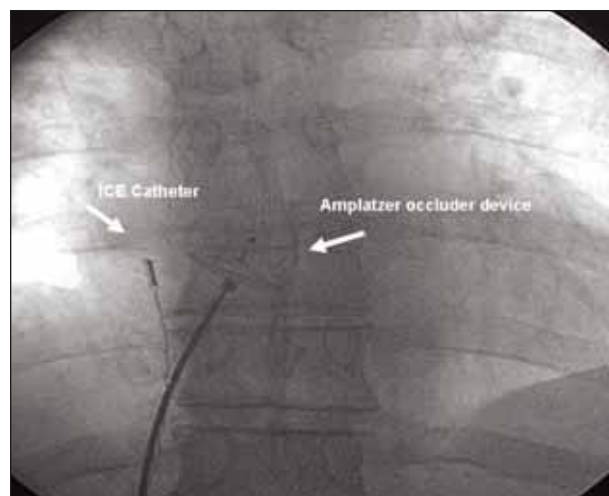


Figure 4. A frame from a training program for atrial septal defect and patent foramen ovale closure showing position of the intracardiac echo catheter and the closure device prior to release from delivery cable.

puncture, interpretation and utilization of transesophageal echocardiography images, and proper device sizing and placement. For the first time, simulation is being used for training operators in a clinical trial investigating the efficacy of a new LAA exclusion device.

Percutaneous Valve Intervention

In no other area of interventional cardiology is the value of medical simulation more important than in the burgeoning area of percutaneous valve management.⁷ The complex array of underlying pathologic mechanisms in the large constellation of valve disorders has challenged device manufacturers to produce an even more complex assortment of unique tools. New technical skills will need to be mastered. The spectrum of regurgitant mitral valve disorders has its origins in a variety of underlying pathophysiologic mechanisms from degenerative changes to annular dilatation to prolapse and papillary muscle dysfunction. Each pathologic mecha-

nism is finding itself host to new, highly specialized, and vastly different interventional solutions. Proposed treatments might involve placement of various restraining devices in the coronary sinus to extrinsically shrink the mitral annulus. Suture- and clip-based methodologies to work directly on mitral leaflets are being explored. Positioning systems using magnets may be involved to facilitate placement of the above leaflet restraints. The required technical skills will be vastly different from those in current practice, requiring far more sophisticated interventional skills.

Percutaneous replacement of stenotic aortic valves is emerging as well. Proposed solutions and unique strategies are expanding continually. An array of balloon-expandable valves will compete with self-expanding technologies. Transapical, transseptal/antegrade, and retrograde solutions are all in development. Each will require very specific critical and very specific deployment strategies. Proper selection of devices will pose its own set of challenges.

TABLE 2. CAROTID SIMULATION TRAINING CENTERS

Program Directors	Practicing Institution	
Michael Jaff, DO	Massachusetts General Hospital	Boston, MA
Dan McCormick, DO	Hahnemann Hospital	Philadelphia, PA
Course Directors	Practicing Institution	
Michael Bacharach, MD	North Central Heart	Sioux Falls, SD
Robert Bersin, MD	Swedish Medical Center	Seattle, WA
Mark Burket, MD	Medical College of Ohio	Toledo, OH
Frank Criado, MD	Union Memorial Hospital	Baltimore, MD
Mark Davies, MD	University of Rochester	Rochester, NY
William Gray, MD	Columbia University	New York, NY
Sheldon Goldberg, MD	Hahnemann Hospital	Philadelphia, PA
Dan McCormick, DO	Hahnemann Hospital	Philadelphia, PA
Richard Heuser, MD	Phoenix Heart Center	Phoenix, AZ
John McB. Hodgson, MD	Phoenix Heart Center	Phoenix, AZ
James Joye, MD	El Camino Hospital	Mountain View, CA
Barry Katzen, MD	Miami Cardiac and Vascular Center	Miami, FL
Zvonimir Krajcer, MD	Texas Heart Center	Houston, TX
Alan Lumsden, MD	Methodist DeBakey Heart Center	Houston, TX
Gregory Mishkel, MD	St. John's Hospital	Springfield, IL
Subbarao Myla, MD	Hoag Hospital	Newport Beach, CA
Bhagat Reddy, MD	Piedmont Hospital	Atlanta, GA
Mark Reisman, MD	Swedish Heart Institute	Seattle, WA
Krishna Rocha-Singh, MD	St. John's Hospital	Springfield, IL
Neil Strickman, MD	Texas Heart Center	Houston, TX
Timothy Sullivan, MD	The Mayo Clinic	Rochester, MN
Mark Wholey, MD	Shadyside Hospital	Pittsburgh, PA

Careful device selection will eventually require a knowledge base that in itself has yet to be defined. The classic proctor-facilitated watch-one/do-one approach to interventional training will be inadequate. The medical simulation environment with three-dimensional "real-time" challenges presenting operators with all of the complexities involved will be indispensable. In addition, there will be great challenges in the maintenance of unique and infrequently used skill sets, which are critical for specific devices. As in the airline industry, attainment and skill maintenance can be achieved with simulation.

Thoracic and Abdominal Aortic Endovascular Repair

There are rapidly developing technologies for the endovascular treatment of aortic aneurysmal disease, and it has been estimated that 35% of all AAAs are treated by a minimally invasive approach.⁸ With the expanding application of this technology to ruptured AAAs, complex aortic anatomy, and the need for repeat interventions, secondary procedures, and the management of endoleaks, advanced technical skills will need to be developed. However, these programs are difficult to access because of limited training

and access to operating suites.

The recent release of an FDA-approved device for the treatment of thoracic aortic aneurysms will require the acquisition of catheter skills, as well as recognition of endovascular approaches to acute and chronic thoracic aortic dissection, and the limitations and complications of treatment in this area.

Simulation training programs are being developed that will provide broader access to structured and reproducible training and more comprehensive exposure to the broad repertoire of catheter skills required to master this expanding field of endovascular medicine. This approach eliminates the need for animal/cadaver lab training and allows physicians to experience important rare procedural adverse events and complications without patient risk.

SUMMARY AND CONCLUSIONS

Given the array of new techniques available for treating cardiac and vascular disease, simulation is a powerful tool that can provide unique educational and training opportunities. We believe that simulation should be a required component for all new procedural training. The educational formats include substitution of simulation cases for traditional

Indications

The AneuRx Stent Graft System is indicated for the endovascular treatment of infrarenal abdominal aortic or aorto-iliac aneurysms having:

- Adequate iliac/femoral access
- Infrarenal nonaneurysmal neck length of greater than 1 cm at the proximal and distal ends of the aneurysm and an inner vessel diameter approximately 10–20% smaller than the labeled device diameter
- Morphology suitable for endovascular repair
- One of the following:
 - (1) Aneurysm diameter of >5 cm
 - (2) Aneurysm diameter of 4–5 cm which has also increased in size by 0.5 cm in the last 6 months
 - (3) Aneurysm which is twice the diameter of the normal infrarenal aorta.

Contraindications

There are no known contraindications currently associated with this device.

Warnings and Precautions

The AneuRx Stent Graft is intended to prevent rupture of abdominal aortic aneurysms. However, this risk is not completely eliminated. Based on reports received for patients enrolled in all phases of the clinical study, through August 1, 2001, ruptures have occurred in 2/1193 patients (0.167%) during the operative period; in 3/1193 patients (0.251%) within 30 days of the treatment; and in 10/1193 patients (0.838%) greater than 30 days after treatment. The one-year freedom-from-rupture rate for patients enrolled in all phases of the clinical study is 99.5%; the two-year freedom-from-rupture rate is 98.6%; and the three-year freedom-from-rupture rate is 98.5%; and the four-year freedom-from-rupture rate is 98.5%.

The long-term safety and effectiveness of this implant have not been established. All patients with endovascular aneurysm repair must undergo periodic imaging to evaluate the stent graft, aneurysm size and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.

Exercise care in the handling and delivery technique to aid in the prevention of vessel

rupture. If an AneuRx Stent Graft is placed with less than one centimeter length of non-aneurysmal tissue at the proximal or distal end attachment sites, there is potential for leaking or migration due to inadequate apposition of the stent graft.

Inappropriate patient selection may contribute to poor device performance. Preliminary data indicate that patients with an aortic neck angle >45 degrees may have a higher likelihood of suboptimal outcomes compared to patients with an aortic neck angle <45 degrees. The same data indicate that patients with an aortic seal length of <15 mm and an iliac seal length of <25 mm may also have a higher likelihood of suboptimal outcomes.

This device should only be used by physicians and teams trained in vascular interventional techniques, including training in the use of the device.

Do not use the AneuRx Stent Graft in patients unable to undergo the necessary preoperative and postoperative imaging and implantation studies.

The results of the clinical studies indicated that patients who experience an unsuccessful endovascular repair attempt, and as a result undergo conversion to surgical abdominal aortic aneurysm (AAA) repair, are likely to have increased complications arising from both procedures (i.e., cardiac complications, fever, infection, musculoskeletal complications, neurological complications, pulmonary complications, vascular disease, vessel dissection, wound healing issues and mortality).

The safety and effectiveness of the AneuRx Stent Graft System for the treatment of abdominal aortic aneurysms have not been evaluated in patients:

- With aneurysms pending rupture
- With connective tissue disorder
- With hypercoagulability
- With mesenteric artery occlusive disease
- With ilio-femoral, thoracic, or inflammatory aneurysms
- With juxtarenal AAA
- With suprarenal or thoracoabdominal aneurysms
- Who are morbidly obese
- Pregnant or nursing
- Less than 18 years old
- With less than one-year life expectancy.

Always have a vascular surgery team available at institutions performing endovascular grafting in the event that conversion to open surgical repair is required.

Patient Selection, Treatment and Follow-up

Do not use this device in patients having an active systemic infection. Do not use this device in patients with sensitivities or allergies to the device materials. The materials include: polyethylene-terephthalate (PET), nickel, titanium, tantalum, stainless steel, polyetheresterblock-copolymer (Hytrell), polyetherblockamide (Pebax), polyetheretherketone (PEEK), platinum, ethyl cyanoacrylate, polymethylmethacrylate and hydroquinone.

The results of the clinical study indicate that women treated with this device may have a higher mortality rate as compared to their male counterparts.

The use of this device requires administration of radiographic agents. Patients with preexisting renal insufficiency may have an increased risk of renal failure postoperatively.

Proper use of this device requires accurate fluoroscopic imaging. This device is not recommended for patients whose weight exceeds 350 lbs (150 kg) or whose weight may impede accurate fluoroscopic imaging.

Regular follow-up including imaging of the device should be performed every 3 to 6 months for patients in the enhanced surveillance group and at least every 6 to 12 months for patients in the routine surveillance group (see IFU for patient follow-up recommendations). During the recommended follow-up imaging schedule, patients should be monitored for aneurysm size, occlusion of vessels, change in pulsatility, migration, leaks and device integrity.

Additional treatment including endovascular treatment or surgical conversion should be strongly considered in the following cases:

- Aneurysm growth >5 mm (with or without leak) since last follow-up
- Change in aneurysm pulsatility (with or without growth or leak)
- Persistent endoleak with or without aneurysm growth
- Stent graft migration resulting in an inadequate seal zone.

The results of the clinical study indicate that subjects experiencing reduced blood flow through the graft limbs and/or leaks may be required to undergo secondary interventions or minor surgical procedures.

MRI may be used on the stent graft only under the following conditions:

- When used in shielded MRI

systems with static magnetic fields of 1.5T or less

- Spatial gradient of 450 gauss/cm or less, gradient magnetic fields of 10 Tesla/second or less
- A maximum whole body averaged specific absorption rate (SAR) of 1.4 W/kg for 30 minutes of imaging.

Adverse Events

Death, AAA rupture, bleeding, cardiac failure/infarction, edema, wound healing complications, impotence, pulmonary complications, renal failure, gastrointestinal complications, arterial vascular occlusion and venous vascular occlusion.

Potential adverse events include: arterial and venous occlusion (includes thrombosis and thromboembolism), arterial trauma/dissection/perforation, bleeding, cardiac failure/infarction, central or peripheral nervous system impairment, coagulopathy, death, edema, endoleak, erosion with fistula or pseudo-aneurysm, gastrointestinal complications, graft dilatation, graft migration, graft occlusion, impotence, infection, loss of device integrity (stent fractures, graft wear holes and suture breaks), pulmonary/respiratory complications, renal insufficiency/failure, ruptured vessel/aneurysm, and wound healing complications.

Please reference appropriate product *Instructions for Use* for a more detailed list of indications, warnings, precautions and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.



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live cases as well as the use of simulators to train and test the competence of individual operators.

The goal of simulation should be to enhance education by providing exposure to new technologies, teach effective methods to prevent and deal with complications, and improve medical care without risk to patients. ■

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