Stroke remains a disabling and sometimes lethal disorder. It is estimated that 800,000 strokes occur each year in the United States, it is currently the fourth-leading cause of death in the country. Historically, strokes have been directly responsible for the deaths of 9 US presidents, and Franklin Roosevelt and Woodrow Wilson both had strokes while in the White House.

Stroke, dementia, and orthopedic fractures due to falls remain the most frequent causes for institutionalization and prolonged nursing home care. The causes of stroke are varied and include hemorrhagic and ischemic mechanisms (Table 1).

Particularly in the older population, non-rheumatic atrial fibrillation (AF) has become an increasingly important contributor to stroke incidence. More than 30% of strokes in individuals over the age of 75 years are due to AF. Multiple stroke risk factors in nonrheumatic AF patients have been identified; these factors are additive (similar to coronary risk factors) and have served as a basis by which practitioners decide to prescribe oral anticoagulants (OACs), chiefly warfarin, over the last several decades.

The CHADS₂ scoring system (and more recently CHADS-VASc) has served as a guidepost for initiation of OAC therapy. Patients who have AF and a CHADS₂ score of 2 to 6 are advised to initiate OAC therapy, as they have an annualized stroke risk of 4% to 18%. Risk reduction of 70% can be achieved with such a program, achieving annualized risks of 1.2% to 5.4%. (The CHADS₂ score is calculated as follows: congestive heart failure, 1 point; hypertension, 1 point; age > 75 years, 1 point; diabetes, 1

---

**Table 1. Etiology of stroke.**

<table>
<thead>
<tr>
<th>Embolic or Thrombotic</th>
<th>Hemorrhagic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Arch Atherosclerosis</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Carotid &amp; Vertebral Atherosclerosis</td>
<td>Trauma</td>
</tr>
<tr>
<td>Intracerebral Atherosclerosis</td>
<td>Anticoagulant Therapy</td>
</tr>
<tr>
<td>Aneurysmal Vascular Disease</td>
<td>Aneurysmal Vascular Disease</td>
</tr>
<tr>
<td>Ventricular Thrombi</td>
<td>AVMs</td>
</tr>
<tr>
<td>Vascularitis</td>
<td>Cancer</td>
</tr>
<tr>
<td>Left Atrial Appendage</td>
<td>Amyloid Angiopathy</td>
</tr>
<tr>
<td>LA Septal Pouch</td>
<td>Illicit Drugs (Cocaine)</td>
</tr>
<tr>
<td>Cardiac Tumors</td>
<td></td>
</tr>
<tr>
<td>Cardiac Vegetations</td>
<td></td>
</tr>
<tr>
<td>Paradoxical Venous due to PFO</td>
<td></td>
</tr>
<tr>
<td>Cardiac Devices</td>
<td></td>
</tr>
<tr>
<td>Procedural/Surgical</td>
<td></td>
</tr>
<tr>
<td>Hypercoagulability</td>
<td></td>
</tr>
</tbody>
</table>
The traditional approach to these patients has been warfarin (Coumadin®) therapy, but this drug notoriously also poses a significant hemorrhagic hazard, particularly in older patients who are on multiple other medications. Warfarin has a narrow therapeutic index, interacts with several other drugs, is affected by dietary alterations, is difficult to regulate at times, and requires regular blood-test monitoring with the international normalized ratio (INR).

The more recently released novel oral anticoagulants (NOACs)—dabigatran (Pradaxa®), rivaroxaban (Xarelto®), and apixaban (Eliquis®)—have all displayed similar efficacy to warfarin for stroke prevention in nonrheumatic AF patients in large randomized controlled trials the last 5 years. Additionally, apixaban was demonstrated to have had a lower bleeding risk when compared with warfarin in the ARISTOTLE trial. However, the full adoption of the NOACs as alternatives to warfarin has been tempered by relative costs, lack of reversal agents for bleeding complications (currently under development), renal clearance requiring dosing adjustments in the elderly, and rebound pro-coagulation phenomena upon drug cessation in some individuals. Nevertheless, the NOACs remain a promising class of pharmacologic agents meriting further evaluation and adoption as an alternative to warfarin.

Many AF patients remain at high risk of bleeding complications from oral anticoagulation regardless of the agent, and thus remain untreated or minimally treated (antiplatelet agents such as aspirin or clopidogrel) prophylactically against thromboembolic stroke. The HAS-BLED bleeding risk scoring system can identify such patients (Table 2).

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Points</th>
<th>Annual Bleed Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>1</td>
<td>3.4%</td>
</tr>
<tr>
<td>Renal Dysfunction</td>
<td>2</td>
<td>4.1%</td>
</tr>
<tr>
<td>Liver Disease</td>
<td>3</td>
<td>5.8%</td>
</tr>
<tr>
<td>Stroke</td>
<td>4</td>
<td>8.9%</td>
</tr>
<tr>
<td>Labile INR</td>
<td>5</td>
<td>9.1%</td>
</tr>
<tr>
<td>Elderly</td>
<td>0</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

Table 2. HAS-BLED scoring system for bleeding on warfarin.
is thought to diminish by > 90%. Results from 1 surgical series did caution about the need for complete closure, as only 45% and 72% were completely closed using suture and stapling techniques, respectively. These patent LA-LAA channels could still act as clot repositories, susceptible to thromboembolization. Surgical devices such as the TIGERPAW® and AtriClip® can assist surgeons who choose to exclude rather than amputate the LAA in the operating room setting.

Available Devices
Three percutaneous devices to facilitate LAA closure have been developed and are in use: WATCHMAN®, Amplatzer®, and LARIAT® (Figure). The only randomized data so far generated using these devices is for the WATCHMAN LAA plug.

The WATCHMAN is a nitinol cage that is placed via a transseptal LA endocardial sheath into the orifice of the LAA. With release after deployment, the cage radially expands with 10 active fixation anchors to maintain positioning and closure of the LAA orifice. The cage comes in 5 different sizes and will contour to most LAA anatomic variants. The device can be placed in patients with prior cardiac surgery. Device endothelization occurs within 6 weeks, and 45 days of OAC is generally prescribed until this healing process has ensued. In 2009, David R. Holmes Jr., MD, cardiologist at Mayo Clinic’s campus in Rochester, Minnesota, and coworkers reported results from the randomized clinical trial PROTECT AF; noninferiority of the WATCHMAN device as compared with warfarin therapy for stroke prevention was shown. A beneficial effect on mortality appears to be emerging with multiyear follow-up of such patients. US Food and Drug Administration (FDA) approval of the device is tentatively expected this year.

The Amplatzer plug has been utilized for percutaneous patent foramen ovale (PFO) closure and also has been adopted as a method for LAA exclusion, though no randomized clinical trial of its use for this indication currently exists.

The LARIAT device is placed using a combined percutaneous endocardial and epicardial approach. A transseptal left atrial endocardial sheath delivers an occlusive balloon catheter that allows angiographic imaging of the LAA and subsequent delivery to its tip of a magnetic wire element; simultaneously, the pericardial space is accessed from a percutaneous subxiphoid approach, and a second magnetic wire element is delivered to the outside of the LAA tip. The 2 magnets attract each other, and then act as a "rail" over which the LARIAT suture is conveyed to the base of the LAA, where the suture is tightened to facilitate LAA base closure. The magnetic wires are then removed, and the suture cut. The LAA is thus isolated from the LA; it infarcts and gradually atrophies, leaving no virtual space. Closure rates of > 95% have been achieved; randomized clinical trials evaluating this technique are planned to begin later this year. No OAC therapy is required after LARIAT LAA closure. Not all LAA anatomies, as determined by cardiac contrast CT, are appropriate for this technique (LAA size must be < 40 mm and not superiorly directed). Additionally, prior cardiac surgery or pericarditis is a contraindication for this technique, as pericardial access will not be readily accomplished.

LAA exclusion will enhance stroke reduction in high-risk patients with nonrheumatic AF who are not candidates for anticoagulation due to OAC failure or high-risk bleeding potential. "In the next 20 years, the at-risk patient pool will balloon due to population demographics and increased detection of AF due to consumer-based monitoring devices and techniques," says Dr Munger. "LAA exclusion therapy will become a more meaningful and important management tool for minimizing stroke potential in the future."
Endovascular Repair of Complex Aortic Aneurysms

Endovascular aortic aneurysm repair (EVAR) has been shown to reduce blood loss, operative time, length of hospital stay, mortality, and morbidity compared with open surgical repair of infrarenal abdominal aortic aneurysms (AAAs). Anatomical constraints limit the use of EVAR in 30% to 40% of patients because of short necks, excessive angulation, or frank aneurysm involvement of aortic side branches such as supra-aortic trunks (arch aneurysms), visceral arteries (thoracoabdominal and pararenal aneurysms), or the internal iliac arteries.

“Fenestrated and branched stent-grafts allow incorporation of aortic side branches and preservation of end-organ perfusion while achieving aneurysm exclusion with a total endovascular approach,” says Gustavo S. Oderich, MD, director of endovascular therapy and a vascular surgeon at Mayo Clinic’s campus in Rochester, Minnesota. Single-center reports, multicenter registries, and systematic reviews indicate that the technique is reproducible with high rates of technical success and low morbidity and mortality.

Open conventional repair remains the standard treatment for patients with complex aortic aneurysms, but this necessitates extensive dissection, higher clamp site, prolonged visceral ischemia, and more extensive reconstruction. While contemporary series have shown that open repair of thoracoabdominal aortic aneurysms (TAAAs) can be performed with mortality rates in the range of 5% to 15% in high-volume centers, analyses of national and regional datasets have demonstrated more ominous results. In the study by Rigberg and associates on 797 Medicare beneficiaries who underwent elective open TAAA repair in California, the mortality rate was 19% at 30 days and 31% at 1 year.

Dr Oderich and colleagues at Mayo Clinic in Rochester have reported the results of 5,798 Medicare patients who underwent open repair in the United States. Mortality increased from 15% for patients aged 60 to 70 years to 30% for those older than 80 years. Overall, a third of the patients were dismissed home and the remainder required prolonged recovery in rehabilitation centers or nursing homes.

**Endovascular Strategies**

The initial experiences with fenestrated and branched endografts have shown that total endovascular repair is effective and may reduce morbidity rates in patients with arch, thoracoabdominal, and pararenal aneurysms. Most of these devices are not yet available for commercial use in the United States and require a period of customization of 6 to 8 weeks. In the absence of widely available endograft designs, a number of centers have reported on a hybrid technique that applies surgical bypasses to re-route the visceral arteries while endovascular stent-grafts are placed to exclude the aneurysm. While this procedure avoids thoracotomy and in many patients aortic cross-clamping, enthusiasm with early results has been tempered by high morbidity and mortality in most reports. Currently, most centers with access to fenestrated and branched endografts have relegated hybrid procedures to high-risk patients who are candidates for neither total endovascular nor open surgical repair.

**Figure 1. Endovascular options for branch incorporation include fenestrated branched devices for pararenal aneurysms, multi-branched devices for thoracoabdominal aneurysms, and iliac branch devices for aortoiliac aneurysms.**
Definitions
Aortic side branches can be incorporated into stent-grafts using either fenestrations or directional branches. Fenestrations imply side holes in the fabric of the stent-graft. These are reinforced by a nitinol ring to facilitate catheterization, prevent fraying of the fabric, and allow attachment of a side branch alignment stent.

The term fenestrated endovascular repair is applied when a fenestrated stent-graft is used to repair an aneurysm with an inadequate or short infrarenal neck, yet the target vessels (for example, renal arteries) arise from a normal segment of the aorta. There is no gap between the fenestration and the target vessel; an alignment stent is typically inserted into side branches to prevent vessel occlusion or stenosis from misalignment between the fenestration and the origin of the target vessel.

Directional or cuffed branches imply the presence of presewn cuffs in the main aortic stent-graft, which serve as a docking site for placement of stent-grafts connecting the main aortic component into each of the side branches. Whereas fenestrations are usually connected with balloon-expandable stents, branches are bridged by self-expandable stent-grafts.

Branched endovascular repair is the term used to describe endovascular repair of aneurysms with involvement of side branches. The target vessel originates from the aneurysm, and there is a gap between the main stent-graft and the aortic wall.

Availability of Devices in the United States
Current designs allow incorporation of almost any large-diameter aortic side branch, including aortic arch, visceral, and internal iliac arteries. In the United States, access to fenestrated and branched stent-grafts is limited to a few institutions. The Zenith fenestrated stent-graft (Cook Medical Inc.) was approved for commercial use by the US Food and Drug Administration in April 2012. This device is indicated for short-neck infrarenal or juxtarenal aneurysms, allowing a maximum of 3 custom-made fenestrations built into the device. While this represents a significant advance, patients with more complex aneurysms, such as those with pararenal, paravisceral, or thoracoabdominal aneurysms, are not candidates for this device. In these patients, fenestrated and branched stent-grafts are available under physician-sponsored investigational device exemption (PS-IDE) protocols or industry-sponsored trials.

Preoperative Evaluation
A comprehensive evaluation of cardiac, pulmonary, and renal performance is a crucial component in optimal patient selection. These procedures are often indicated in the sickest patients, but clinical data suggests that benefits may be higher in low- or intermediate-risk patients. Prohibitive high-risk patients and those with limited life expectancy are not ideal candidates. The evaluation typically includes a noninvasive cardiac stress test, pulmonary function tests, and a carotid ultrasound.

Design and planning is based on careful analysis of aneurysm morphology using high-resolution computed tomography angiography (CTA) with small (1- to 3-mm) cuts. Standard measurements include centerline of flow analysis to determine accurate estimates of lengths, axial clock position, arc lengths, and angles. Device planning starts with the selection of an adequate proximal landing zone based on a “healthy” aorta. A normal aorta should have parallel walls with no calcium or thrombus. In patients with diffuse aortic ectasia, familial history of aortic aneurysm, or minor aortic abnormalities (calcium or thrombus), a generous proximal landing zone of 6 to 8 cm is recommended above the level of the celiac axis.

Juxtarenal or Pararenal Aortic Aneurysms
Aneurysms involving the renal arteries but not extending beyond the superior mesenteric artery are repaired using fenestrated stent-grafts. The Zenith fenestrated stent-graft has been approved for treatment of patients with > 4 mm neck below the renal arteries, but these devices can be fashioned with more fenestrations in centers with PS-IDE protocols. Based on contemporary results, technical success is greater than 99%, with average 30-day mortality of 1.5% (0%-4%).

Attachment endoleaks are infrequent, occurring in less than 2% of patients, but approximately 15% to 20% may have a retrograde endoleak via the lumbar arteries. These are typically observed or treated by percutaneous coil embolization if there is evidence of aneurysm sac growth. Patency of visceral branches is exceptionally high, averaging > 95% at 5 years. Secondary intervention rates range between 10% and 20%. Modest deterioration of renal function is not uncommon (up to 25%), though incidence of dialysis is low (0%-3%). Three systematic reviews of the literature have shown that fenestrated repair is associated with significantly lower rates of early mortality and renal dysfunction as compared with open surgical repair.

Thoracoabdominal Aortic Aneurysms
Thoracoabdominal aneurysms extend across the visceral arteries and represent the most complex form of aortic aneurysm. Technical difficulty is determined by extent of aortic involvement, visceral occlusive disease, tortuosity, and iliac access issues. Type I and Type II TAAAs involve the entire thoracic aorta extending distally to or beyond the renal arteries, respectively. Type III TAAAs start below the T6 level and extend beyond the renal arteries. Type IV TAAAs are the simplest form, starting at the level of the celiac axis and extending distal into the infrarenal aorta or iliac arteries. The extent of aortic involvement has direct implications for choice of technique (fenestrated or branched) and risk of spinal cord injury, which ranges from 1% to 2% for Type IV TAAAs and up to 10% for Type II TAAAs.

Figure 2. Extensive thoracoabdominal aneurysm after prior infrarenal aortic repair was treated by a branched endograft with 2 branches for the celiac and superior mesenteric arteries and fenestrations for the renal arteries.
Device design can be done with fenestrations, branches, or both. Each design has its own advantages and disadvantages. Fenestrations are optimal for renal arteries and for vessels that originate from a narrow aortic lumen, while branches are ideal for the celiac and superior mesenteric arteries or for branches that originate from large aortic lumen.

Contemporary reports have shown that branched stent-grafts can be performed with high technical success (93%-100%). Mortality averages 4% in systematic reviews, ranging from 0% to 18% in single-center reports. Incidence of dialysis averages 2%, ranging from 0% to 8%. Spinal cord injury has been improved by staged repair, which allows conditioning of spinal cord collaterals with paraplegia rates of 5% in the most extensive (Type II) TAAs. Visceral branch patency is > 95%. Secondary interventions are required in 10% to 15% of patients.

Aortoiliac Aneurysms
Approximately 30% of patients treated by EVAR have ectatic or aneurysmal common iliac arteries, which are not suitable to seal the stent-graft. In these patients, one of the most commonly utilized options is unilateral or bilateral internal iliac artery exclusion, allowing extension of the stent-graft into the external iliac artery. Buttck claudication may occur in 16% to 50% of patients treated by unilateral and up to 80% of those undergoing bilateral embolization. Sexual dysfunction is noted in 10% to 17% of patients. Although uncommon, devastating complications include spinal cord injury, ischemic colitis, and gluteal muscle necrosis. In addition, because the internal iliac artery is an important collateral to the spinal cord, preservation of internal iliac artery flow is critical to prevent paraplegia in patients with concomitant thoracic or thoracoabdominal aortic aneurysms. Results of iliac branch stent-grafts have been encouraging, with technical success rates of greater than 95% in most reports and branch patency rates of more than 95% at 5 years.

Summary
"Endovascular repair of complex aneurysms involving the visceral arteries has become a reality," says Dr Oderich. "Fenestrated stent-grafts are increasingly utilized to treat pararenal and thoracoabdominal aneurysms. The technique is safe, effective, and can be performed with high technical success and low risk of complications by experienced physicians." More than 8,000 patients have been treated by fenestrated and branched stent-grafts and more than 5,500 by iliac branch devices. Based on results of single-center reports, systematic reviews, and the US prospective trial, technical success is high (> 98%) with low rates of type I and type III endoleak, migration, aneurysm rupture, and conversion to open repair. Branch patency averages > 95% with covered stents. These results should serve as a benchmark for comparison with alternative endovascular techniques of branch vessel incorporation, including debranching, snorkel, and physician-modified grafts. "Long-term comparison with open surgical repair is still required," says Dr Oderich.

Clinical trials and physician-sponsored investigational device exemption (PS-IDE) protocols are available at Mayo Clinic to treat arch, thoracoabdominal, and pararenal aneurysms using manufactured fenestrated and branched stent-grafts. For more information about clinical trials utilizing these devices in the treatment of aortic aneurysms at Mayo Clinic, contact:

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Jesse E. Edwards, MD, joined the staff of Mayo Clinic in 1946. He received his medical degree from Tufts University, completed a pathology residency in Boston, Massachusetts, and then served as a research fellow at the then-brand-new National Cancer Institute in Bethesda, Maryland.

Joining the Army during World War II, he served as a pathologist on the war crimes investigation team and ultimately as director of laboratories for the European Theater. Hired by Mayo as a cancer pathologist, he was attracted to a small collection of hearts with congenital defects. Because the field of cardiac surgery was just beginning, his chief suggested he review the hearts and he "might get a paper or two out of the review."

The 1950s and 1960s were a golden age for the study of cardiac disease. The first cardiac catheterization at Mayo Clinic was performed in 1947. The development of the Mayo-Gibbon heart-lung bypass machine allowed for surgical treatment of congenital and acquired heart disease. Dr Edwards' initial review of the Mayo hearts began a collaboration with cardiac surgeons, cardiologists, and physiologists that would continue throughout his life and sowed the seeds for the integrated cardiovascular practice that continues to this day at Mayo Clinic.

"It was easier back then to take advantage of all of the great medicine going on," Dr Edwards said in 2008. "There were no turf wars, and we were all learning together."

As a child growing up during the Great Depression, Dr Edwards learned early not to waste anything. He viewed the opportunity to study and learn from hearts obtained at autopsy as a sacred responsibility—a way to make additional contributions to the world from the patient who was deceased. The informal collection of hearts eventually became formally organized as the Edwards Cardiovascular Registry, which now includes more than 22,000 specimens, including not only hearts but also cardiac valves, blood vessels, and lungs. This collection allowed pathologists, cardiologists, and cardiac surgeons to see and study the cardiac diseases and malformations they were treating.

Lyle D. Joyce, MD, PhD, cardiothoracic surgeon at Mayo Clinic's campus in Rochester, Minnesota, trained with Dr Edwards during his surgical residency. "I was most impressed with his thorough understanding of the impact that various diseases have on the heart," Dr Joyce says. "He could take a specimen and piece together most of the details about the patient just by studying the parts of the heart."

Dr Edwards was the first pathologist to serve as president of the American Heart Association (1967-1968). He published more than 700 peer-reviewed manuscripts and authored 12 books throughout his career, including 2 groundbreaking references: his 3-volume "An Atlas of Acquired Diseases of the Heart and Great Vessels," and his 2-volume "Congenital Heart Disease." He published 2 books after age 90 and was still writing at the time of his death in 2008 at age 96. Throughout his life, Dr Edwards took great pride in the success of his many students. His collection survives intact at the Jesse E. Edwards Registry of Cardiovascular Disease in St. Paul, Minnesota.

**RECOGNITION**

Jane A. Linderbaum, RN, CNP, member of the Division of Cardiovascular Diseases at Mayo Clinic's campus in Rochester, Minnesota, was selected by the Awards Committee and Board of Trustees of the American College of Cardiology (ACC) to receive the 2014 Distinguished Associate Award in recognition of her outstanding contributions to the college and the field of cardiology that have nurtured the ACC's team approach to cardiovascular care.
Continuing Medical Education, Mayo Clinic
For additional information:
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Email: cvcme@mayo.edu
Phone: 800-283-6296

Cardiology Update 2014: The Heart of the Matter
Jul 31-Aug 3, 2014
Sedona, AZ

Success With Heart Failure: Strategies for the Evaluation and Treatment of Heart Failure in Clinical Practice
Aug 11-13, 2014
Dana Point, CA

19th Annual Mayo Clinic Cardiovascular Review Course for Cardiology Boards and Recertification With Pre-Course Echo Focus Session
Aug 15-20, 2014
Rochester, MN

Pediatric Cardiology 2014 Review Course
Aug 17-22, 2014
Dana Point, CA

Electrophysiology Review for Boards and Recertification
Sep 5-8, 2014
Rochester, MN

Clinical and Laboratory Update in Thrombosis, Anticoagulation, and Vascular Medicine: A Board Review Primer
Sep 10-12, 2014
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Challenges in Clinical Cardiology: A Case-Based Update
Sep 12-14, 2014
Chicago, IL

Echo at the Arch: Practical Review of Valvular Heart Disease
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St. Louis, MO

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Sep 26-28, 2014
Rochester, MN

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Oct 10-11, 2014
Boston, MA

Advanced Cardiovascular Imaging 2014: Interactive and Case-Based Review
Oct 10-11, 2014
Amelia Island, FL

30th Annual Echocardiography in Pediatric and Adult Congenital Heart Disease
Oct 15-19, 2014
Phoenix, AZ

6th Annual Cardiology Conference
Oct 17-18, 2014
La Crosse, WI

Oct 18-21, 2014
San Francisco, CA

24th Annual Cases in Echocardiography, Cardiac CT and MRI
Oct 22-25, 2014
Napa, CA

Coronary Artery Disease: Prevention, Detection & Treatment
Nov 21-23, 2014
Las Vegas, NV

Echo on Marco Island: Case-Based Approach
Dec 4-7, 2014
Marco Island, FL

3rd Annual Mayo Clinic ECG and Heart Rhythm Course: A Case-Based Approach
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The Heart Beat of Cardiology: Practical Application of Echocardiography
Dec 11-13, 2014
Chicago, IL

SYMPOSIA
Mayo Clinic Satellite Educational Symposia at AHA 2014
Nov 15-19, 2014
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Symposia to be announced

CARDIOVASCULAR SELF-STUDY
https://cardiovascular.education-registration.com/selfstudy