A New Era in the Management of Aortic Stenosis

Robert N. Piana, M.D., David Zhao, M.D., Marzia Leacche, M.D., and John Byrne, M.D.

Aortic stenosis (AS) is a disease of the elderly with a prolonged, insidious development over decades. With an aging population in developed countries, the prevalence of AS is estimated at 5% to 7% among the elderly. Most commonly, AS results from calcification of the aortic valve beginning at the base of the cusps and extending to the leaflets, progressively restricting leaflet motion without true fusion of the commissures. Morbidity and mortality are very low from AS during its latency period. Once symptoms develop (angina, syncope or heart failure), the prognosis changes dramatically. Average survival is two to three years, with a high risk of sudden death.

Aortic valve replacement (AVR) is therefore indicated (Class I recommendation) in virtually all symptomatic patients with severe AS unless serious comorbid conditions preclude surgery.

Despite this recommendation, a prospective survey by the European Society of Cardiology found that in practice AVR was actually not performed in 30% of patients with severe AS. This guideline-practice gap highlights the complex nature of patients with AS. Advanced age, severe pulmonary and renal disease, recent myocardial infarction, significant ischemic heart disease, and a short life expectancy were prominent in the unoperated patients in this European registry. Such comorbidities are incorporated into validated models such as the Society for Thoracic Surgery (STS) Risk Calculator or the EuroScore in an effort to predict outcomes of cardiac surgery in an objective manner. The decision not to operate in 30% of severe AS patients in the European survey may therefore reflect good clinical judgment. Simultaneously, it emphasizes the unmet need for potentially safer approaches than AVR for the high-risk patient with severe AS.

Transcatheter aortic valve implantation (TAVI) has been pioneered as a novel alternative to traditional AVR for this patient population. Since Criber first reported TAVI in 2002, this therapeutic option has become popular in Europe and has proven to be a feasible technique in selected patients. The two most commonly used trans-catheter aortic valves are the Edwards Sapien® Valve (Edwards Lifesciences, Irvine, CA) (Figure 1) and the Core-Valve® ReValving System (Medtronic, Minneapolis, MN) (Figure 2).

(Continued on page 4)
A truly transformational change is under way in the management of complex valvular heart disease. Vanderbilt Heart and Vascular Institute (VHVI) is uniquely positioned to lead this paradigm shift in the Southeast due to the exemplary collaboration of cardiac surgeons, interventional cardiologists, cardiac anesthesiologists, and seasoned cardiologists focused on imaging and the non-invasive management of valve disorders.

**Aortic Stenosis (AS)**
In this issue of Vanderbilt Heart, we highlight the revolutionary changes ongoing in the management of AS, the most common valve lesion requiring surgical repair. Without replacement, severe AS carries a grim prognosis with less than one in three patients surviving five years after the development of symptoms. The perioperative mortality of aortic valve replacement at VHVI is approximately 1%, substantially lower than the national average of 4%. However, mortality increases substantially with increasing age, left ventricular dysfunction, and presence of other comorbidities. Recently, transcatheter aortic valve implantation (TAVI) has emerged as an option for patients who are not candidates for traditional valve replacement due to prohibitive operative risk. The CoreValve system is one of the commercially available TAVI systems in Europe. However, this technology is only available in the United States as part of a clinical trial. Fortunately, the FDA has now approved a pivotal U.S. trial of the CoreValve. In recognition of its multidisciplinary expertise, Vanderbilt has been selected as one of only 41 participating centers nationwide, and patient enrollment is under way. This effort will be spearheaded by John Byrne, M.D., Stephen Ball, M.D., David Zhao, M.D., Joseph Fredi, M.D., Mark Robbins, M.D., and Marshall Crenshaw, M.D. Patients with severe AS who are considered high risk for surgical aortic valve replacement will now have novel options for management through this landmark trial.

**Mitral Valve Disease**
VHVI also continues to implement exciting advances in the management of other complex valvular disorders. Traditional mitral valve replacement/repair (MVR) is performed through a midline sternotomy. However, VHVI cardiac surgeons frequently employ a “minimally invasive approach” that utilizes a thoracotomy rather than sternotomy. This technique substantially reduces the procedural morbidity and post-operative recovery time. When concomitant treatment of coronary artery disease is required, a “hybrid procedure” combining coronary stenting and minimally invasive MVR, is often performed at the same sitting. This procedure is performed utilizing a “hybrid operating room,” a concept pioneered at Vanderbilt that stresses patient-centered, rather than procedure-centered, care. VHVI cardiologists also provide percutaneous mitral valvuloplasty to treat rheumatic mitral stenosis in appropriate patients, thereby avoiding surgery.

**Pulmonary Valve Disease**
Pulmonary Valve Disease has historically received little attention. However, the impact of pulmonary valve dysfunction on morbidity and mortality is becoming increasingly recognized, particularly among patients with congenital heart disease. VHVI cardiologists, lead by Thomas Doyle, M.D., Dana Janssen, M.D., and Robert Piana, M.D., perform percutaneous pulmonary valve implantation, providing select patients treatment without undergoing cardiac surgery.
The VHVI Approach

The Valvular Heart Disease Program at VHVI provides comprehensive, collaborative care for the increasingly complex spectrum of valve patients by leveraging partnerships among multiple specialists. The weekly multidisciplinary Valve Conference exemplifies the VHVI approach. In this working meeting, cardiologists and cardiac surgeons convene to discuss cases and develop therapeutic plans for specific patients. After review, there is a determination concerning the need for further testing and whether the patient would be best treated medically, minimally invasively, surgically, or through a hybrid approach combining surgical and percutaneous techniques. The team approach is also highlighted annually at the Vanderbilt Valve Symposium organized by John Byrne, M.D., chair of the Department of Cardiac Surgery. This multidisciplinary conference convenes national experts from cardiac imaging, interventional cardiology and cardiac surgery to promote team-based management of advanced valvular disease. This pervasive, programmatic emphasis on innovation and collaboration positions VHVI as a unique institution for continued breakthroughs in the management of complex valvular heart disease.

There are two major approaches to the placement of trans-catheter aortic valves.\(^1\) (Figure 3) In the “retrograde approach,” percutaneous access and valve placement is performed through one of the femoral arteries and the device is advanced toward the aortic annulus under fluoroscopy. A catheter with a manually activated deflectable tip is used in order to avoid aortic arch injury. The major impediments to this approach include aortic calcification, the presence of large arteromas, or limited femoral access due to peripheral vascular disease. In the “transapical approach,” a small left thoracotomy is made, the sheath is directly inserted into the left ventricular apex and a guidewire is used to cross the aortic valve and deploy the transcatheter valve. The transapical approach is usually used in patients with vascular challenges such as poor peripheral vascular access, severe carotid artery disease, or a calcified (“porcelain”) aorta. As such, its use generally reflects a much higher risk patient group. This approach is best performed in a “hybrid operating room” which combines the facilities of both a cardiac surgery operating room and an interventional cardiology catheterization laboratory, thereby enabling multidimensional treatment options.

### Table: Transcatheter Aortic Valve Technologies

<table>
<thead>
<tr>
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<th>Edwards SAPIEN®</th>
<th>Edwards SAPIEN® XT</th>
<th>Medtronic Revalving® System</th>
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<td>Edwards Lifesciences</td>
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<td>Porcine Pericardium, trileaflet</td>
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<td>Thermafix anticalcification</td>
<td>Standard tissue fixation</td>
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<td>23 mm, 26 mm, 29 mm</td>
<td>26 mm, 29 mm</td>
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<tr>
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<td>18F</td>
<td>18F</td>
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<tr>
<td><strong>Delivery System</strong></td>
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<td>RetroFlex3® (Flex Catheter)</td>
<td>18F distal end, 12F shaft body</td>
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(Adapted from Hara 2010)
The Edwards Sapien® valve has been rigorously studied in the PARTNER trial. Of 3,185 total patients screened, 1,057 patients were enrolled in the two parallel trials. The “High Risk” trial (Cohort A) enrolled 699 high surgical risk patients with severe AS and a predicted operative mortality of ≥15%. Patients were assigned to transfemoral (TF) or transapical (TA) TAVI approach based on anatomic considerations, and then within the TF and TA groups patients were randomized to TAVI versus AVR on a 1:1 basis. The primary endpoint in this non-inferiority trial was all cause mortality at one year. PARTNER enrolled an additional 358 patients with prohibitive surgical risk into an “Inoperable” trial (Cohort B). These patients were randomized 1:1 to transfemoral TAVI versus medical therapy. The co-primary endpoints in this superiority trial were 1) all cause mortality and 2) a composite of all cause mortality plus repeat hospitalization.

The PARTNER inoperable trial (Cohort B) was published in 2010. At 30 days TAVI suffered from a higher incidence of major strokes (5.0% vs 1.1%, p=0.06) and major vascular complications (16.2% vs 1.1%, p<0.001) than medical therapy. However, the one-year results with TAVI were impressive. TAVI reduced all cause mortality at one year from 50.7% to 30.7% (p<0.001) and lowered the composite endpoint of death and rehospitalization from 71.6% to 42.5% (p<0.001).

At the April 2011 American College of Cardiology Annual Scientific Sessions, the PARTNER high risk trial (“Cohort A”) of TAVI versus AVR was reported with tremendous enthusiasm. Notably, 8% of the AVR group withdrew or refused the assigned therapy, while 5% of the TAVI group either had the procedure aborted or converted to surgical AVR. TAVI was associated with a non-statistically significant increase in major stroke at one-year compared to AVR (5.1% vs 2.4%, p=0.07). Most importantly, however, non-inferiority of TAVI with respect to one-year survival was clearly established in this trial. All cause mortality was 24.2% with TAVI and 26.8% with AVR (p=0.62). Interestingly, the observed surgical 30-day mortality was 8%, compared to the expected rate of 11.8% predicted by the STS risk model. TAVI was thus compared to better surgical results than historically achieved. Moreover, this study included the learning phase for TAVI at most centers and used a larger vascular sheath size than is now available. Therefore, TAVI results with the SAPIEN® valve are expected to improve over time.

CoreValve has just published its two-year follow-up data from a multicenter, prospective, single arm study of moderate and high risk patients with severe AS. Technical success was 83.1%, with a 30 day mortality of 15.2%. At two years all cause mortality was 38.1%, and was significantly higher in the high risk groups than in the moderate risk group (45.8% vs 27.8%; p=0.04) attributable to noncardiac mortality. There was no incidence of structural valve deterioration over two years. CoreValve is now initiating its US Pivotal trial. This study will randomize high risk AS patients with a predicted 30-day AVR mortality of ≥15% to TAVI versus AVR. The primary outcome measure will be all cause mortality at one year. In a second cohort, extremely high risk patients with expected surgical mortality/irreversible morbidity of ≥50% will be treated with TAVI. The primary endpoint in this cohort is all cause death and major stroke. Vanderbilt Heart and Vascular Institute (VHVI) was selected as one of 41 sites for this landmark trial, reflecting national recognition of our institutional expertise in complex valvular heart disease, as well as the intensive collaboration between cardiac surgeons and interventional cardiologists at Vanderbilt. Patients are now being recruited.

A new era in the management of AS has clearly dawned. Many challenges remain ahead in this arena, but VHVI is poised to help spearhead the effort to improve clinical outcomes in AS patients through such novel surgical and interventional approaches, beginning with the CoreValve randomized trial.

Maintaining Reliable Function for Implanted Heart Rhythm Devices

Jason Rytlewski, M.D., and Jeff Rottman, M.D.

Pacemaker (PM) and implantable cardiac defibrillator (ICD) therapies have evolved rapidly in the past 20 years and are the standard of care in many clinical situations. More than 2.25 million pacemakers and 400,000 defibrillators have been implanted in the United States alone.¹ These numbers will continue to increase as evolving technology allows for more advanced therapies resulting in expanding clinical indications. While cardiac devices are held to an extremely high standard, device failure and complications can occur on occasion, and physicians must be prepared to manage these situations.

Device Surveillance
Implanted rhythm device management has recently been highly scrutinized due to the unexpectedly high failure rate of the Medtronic Sprint Fidelis (mostly the model 6949) ICD lead and a set of Guidant ICD generators. However, such issues are neither new nor restricted to these components. The Fidelis lead has been found to have a three-year failure rate of 4%-12% within the right ventricular pacing and sensing component²-³, which can lead to device oversensing of “electrical noise” and result in inappropriate ICD shocks. It is estimated that more than 100,000 patients are currently utilizing this lead within their defibrillator system.⁴ It is essential to note, however, that only 61 deaths have been reported and directly linked to a malfunctioning pacemaker or defibrillator system¹ During the same period, tens of thousands of lives have been extended as a consequence of implanted heart rhythm devices, and the quality of life improved for many more patients.

Given the complex issues associated with device therapy, it is vital that these patients receive regular follow up with a team experienced in device management. At Vanderbilt Heart and Vascular Institute (VHVI) we maintain a comprehensive service dedicated to device management, integrating electrophysiologists, cardiac surgeons, advanced practice nurses, device technicians, and 24/7 coverage for immediate management of detected events. Current technology allows the routine transmission of a device interrogation trans-telephonically to the clinic for review. This is especially vital when the patient suspects a shock has been delivered or if the device emits an alarm tone. Furthermore, routine trans-telephonic transmission (usually every 3-6 months) can potentially alert the practitioner to clinically significant events. The newest devices generally transmit notice of alerts and clinically significant rhythm changes automatically, even without patient or physician interaction.

The FDA and device manufacturers currently work together to create “advisories” regarding specific products and any potential defects that may exist in order to inform the clinician. In addition, the FDA mandates that device manufacturers provide an annual report detailing the devices implanted and any reported adverse or unexpected outcomes. Post-market evaluation is a difficult issue in all therapeutics, and devices are no exception. Often advisories are not available until the product has been on the market for several years as it takes time for clinical issues to become evident and the data to accumulate. Efforts now are focused on decreasing this delay, and improving the completeness and accuracy of post-marketing drug and device surveillance. Device programming continually evolves in an effort to improve clinical outcomes, and most advisories specify changes in device follow-up and programming, rather than recommendations for removal. With the Sprint Fidelis 6949 lead, Medtronic created a “Lead Integrity Alert” programming feature that alarms the patient if a sudden change in lead impedance is found with auto-interrogation.
Laser Assisted Device Extraction

While device malfunction is an important clinical problem, device infection continues as a more common and often more devastating clinical situation. Reported rates of device infection vary widely from 0.13%-19.9%. The incidence of device infection appears to be increasing. The reason for this is likely multifactorial with patient age, diabetes, malignancy, chronic kidney disease, anticoagulation and number of leads implanted all contributing. Greater than 80% of these infections are Staphylococcus, Streptococcus, or enterococcus species. These organisms often form a biofilm that is resistant to medical therapy and the only curative measure is typically device extraction and prolonged antibiotic coverage. It should be noted that any implanted device that is exposed to the environment is presumptively infected, and definitive cure almost always necessitates complete removal, and generally replacement, of the entire implanted system (see Figure 1).

Lead extraction may also be required due to vascular occlusions with inability to otherwise place additional needed components, chronic pain, or consequences of venous outflow obstruction. Lead extraction and replacement is performed regularly with more than 15,000 PM/ICD systems extracted worldwide annually. Extraction of these devices can be problematic, however, as they are designed to be permanent.

Device leads implanted several years earlier often require laser lead extraction: an excimer laser sheath is used to preferentially lyse fibrotic adhesions along the lead, facilitating removal (see Figure 2). This tool has been associated with a substantial improvement in the success and safety of lead removal, but significant risk remains and experience is essential. Reported rates of major complications with laser lead extraction vary from 0.4% to 4.0% with major complications including death, cardiac avulsion requiring surgical intervention/pericardiocentesis, vascular avulsion requiring surgical intervention, pulmonary embolism requiring surgical intervention, respiratory arrest, stroke and infection of previously uninfected cardiac device. The incidence of these complications is reduced dramatically with operator experience, with the steepest learning curve occurring with the first 30 laser lead extractions performed, and individual and institutional outcomes improving at least to 400 cases.

The recent consensus statement indicates that laser lead extraction can be an appropriate option depending on the individual clinical situation. This procedure should not be performed, however, unless the operator has performed at least 40 laser extractions under the guidance of a mentor who has performed greater than 175 laser extractions. Furthermore, cardiac surgery should be immediately available in the event that an emergent surgery is required.

VHVI is a designated center of excellence for lead extraction and implanted rhythm device management, with removal of more than 800 leads over the last 6 years. This has been achieved with no procedural mortality, and an exceptionally high rate of procedural success. A core group of electrophysiologists is responsible for this effort, with a long-standing collaborative effort encompassing cardiac surgery and infectious disease, and absolute adherence to the very rigorous guidelines. Superb clinical outcomes remain a central goal of the center, but education for our cardiology and electrophysiology fellows and physicians throughout the region, and research are also essential components.

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![Figure 1: Pacing leads eroded through the skin.](image1)

Once exposed externally, implanted device components are infected, and complete removal is generally required. Indolent infection may also be the underlying factor in causing an infection.

![Figure 2: Extracted atrial pacing and ICD leads.](image2)

The laser sheath has isolated the leads from their encasing fibrotic adhesions.
Dabigatran, a Novel Anticoagulant for Non-Valvular Atrial Fibrillation

James A. S. Muldowney III, M.D., F.A.C.C.

For more than 50 years, warfarin has represented the only choice available for long-term anticoagulation, and as a consequence, is one of the top 20 drugs most commonly prescribed in the United States. This agent has found utility in the treatment of myocardial infarction, stroke, venous thromboembolic disease and, in the 1990s, atrial fibrillation. The challenges associated with the use of warfarin stem from the need to monitor and adjust the dose of the medication in order to maintain a steady level of anticoagulation. Changes in diet and concomitant medications can affect warfarin levels resulting in significant inter-individual variability in warfarin dose to achieve the same level of anticoagulation in different patients. As a consequence, complications from warfarin therapy represent one of the most frequent causes of medication-related morbidity and mortality in the United States.

In December, the Food and Drug Administration (FDA) approved a new oral anticoagulant, Pradaxa™ (dabigatran etexilate), for the treatment of non-valvular atrial fibrillation. Dabigatran is a direct thrombin inhibitor, preventing the conversion of fibrinogen to fibrin. Dabigatran is a fixed dose medication (150 mg, twice daily, in individuals with an estimated glomerular filtration rate (eGFR) > 30 ml/min or 75 mg twice daily in individuals with an eGFR 15-30 ml/min, contraindicated in individuals with an eGFR < 15 ml/min) that does not require monitoring. The only clinically relevant drug interaction is with rifampin, which decreases bioavailability of the drug. There are no relevant cytochrome P450 interactions. The most frequent side effects are dyspepsia and bleeding.1

The medication is impregnated on tartaric acid granules and encapsulated, as an acidic environment enhances absorption. The capsules should not be opened as this dramatically enhances bioavailability, and increases risk of bleeding.

Dabigatran is renally cleared, so the pharmacokinetics are highly predictable. Patients are fully anticoagulated one to two hours after the first dose of the medication. Patients with essentially normal renal function (eGFR > 50 ml/min) eliminate the drug in sufficient quantities so that holding the medication for 48 hours is adequate for elective surgery. For operations with potentially catastrophic effects from untoward bleeding, such as spinal surgery, the drug should be held for at least 60 hours to ensure optimal hemostasis. The medication should be held longer in patients who are renally impaired in preparation for elective surgery. Similarly dabigatran should be restarted after surgery when the patient is ready to be fully anticoagulated. This is usually a few days after warfarin would normally be started.

Initiating dabigatran in patients on warfarin should be done after the INR has been allowed to drift down below 2.0. Patients on enoxaparin should start dabigatran 12 hours after their last dose of the parenteral anticoagulant. Similarly enoxaparin should be started on patients transitioning from dabigatran 12 hours after the last dose of the oral agent. Transitioning from dabigatran to warfarin is based the patient’s renal function.

In the event of bleeding associated with dabigatran, holding the drug is the best antidote along with supportive measures such as surgical hemostasis, plasma, and, if appropriate, platelets. In extreme cases, the medication can be dialyzed off, and clotting factor concentrates can be administered.

Dr. Muldowney is the site PI for the COAG trial, a study of pharmacogenetic-based dosing of warfarin sponsored by NHLBI. He has grants from the NIH and Novartis and has received speaker fees from Boehringer Ingelheim.
The RE-LY trial was the pivotal study that led to FDA approval of dabigatran in non-valvular atrial fibrillation. This was a study of more than 18,000 subjects with atrial fibrillation. Patients (mean CHADS2 score was 2.2) were randomized to open label warfarin, or dabigatran 110 mg twice daily or 150 twice daily and followed for up to 30 months. The patients in the warfarin arm had an event rate (stroke or thromboembolic event) of 1.7%/year while the dabigatran 150 mg arm enjoyed a 1.1%/year event rate (P < 0.001 for superiority). Major bleeding was similar in both arms (3.6% for warfarin compared to 3.3% for dabigatran (P = NS), while life-threatening bleeding and intracranial hemorrhage rates were lower in the dabigatran arm. Gastrointestinal bleeding was higher in the dabigatran arm. There was a higher discontinuation rate in the dabigatran arm that was driven by early discontinuations (in the first six months). However, the rates of discontinuation were parallel after six months. There were more than 1,900 cardioversions performed during the RE-LY trial and it appeared that stroke rates were similar in both arms.2

It is not unreasonable to speculate that dabigatran may achieve FDA approval in the near future for the treatment of acute venous thromboembolic disease (VTE). The RE-COVER trial is a double-blind randomized control trial in about 2,500 subjects comparing warfarin to dabigatran 150 mg BID in the treatment of acute deep venous thrombosis and pulmonary embolus. Patients received blinded dabigatran or warfarin for six months. The primary endpoint was recurrent VTE or death over the six-month period. Dabigatran was found to be non-inferior to warfarin with regard to the primary endpoint. There were similar rates of major bleeding in both arms but less total bleeding in the dabigatran arm.3

Dabigatran represents a novel and reasonable alternative to warfarin in patients with non-valvular atrial fibrillation. Along with the investigational oral factor Xa inhibitors, apixaban and rivaroxaban, Dabigatran ushers in an exciting new era in anticoagulation.


Maintaining Reliable Function for Implanted Heart Rhythm Devices

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Current research initiatives include improving risk prediction models to better guide decisions about elective lead removal in response to advisories, and hybrid catheter-surgical approaches for leads when transvenous approaches alone are insufficient.

Ultimately, the best solution is the prevention of device malfunction or infection when possible. Prophylactic antibiotics are often administered at the time of implantation, although no large, randomized controlled trial has ever been performed demonstrating benefit. In patients at a higher risk for infection, an antibiotic sleeve can be placed around the device at the time of implantation. National registries with device malfunction reporting are also essential tools in the early detection of patterns of device failures.

Addressing individual device-related problems, while minimizing individual adverse outcomes, is essential to maintaining the compelling benefit demonstrated in many trials for ICDs and other heart rhythm devices. We believe this “personalized medicine” approach by the Arrhythmia Service at VHVI will continue to optimize care for patients with implanted cardiac rhythm devices in Middle Tennessee.

The Radial Approach to Cardiac Catheterization and Intervention

Elias Haddad, M.D., and Pete Fong, M.D.

The use of the radial artery for coronary angiography and percutaneous coronary intervention (PCI) was first described in the literature by Lucien Campeau in 1989.\(^1\) In the last two decades the use of radial artery access has remained the exception rather than the rule in most U.S. centers despite data showing a decrease in complications and improved patient satisfaction with radial access. The radial artery is a superficial structure with no major adjacent vessels. This anatomy appears to enhance the safety of cardiac catheterization significantly. In a meta-analysis of 14 transradial studies, vascular complications were reduced by 80% compared to femoral access.\(^2\) Radial access has also been shown to decrease length of hospital stay following coronary intervention and to lower cost of care.\(^3, 4\)

The importance of reducing bleeding complications is becoming increasingly understood. Access site complications such as hematomas, dissections, pseudoaneurysms and retroperitoneal bleeds have a major impact on clinical outcomes. A recent analysis of patients from four major published acute coronary syndrome (ACS) trials showed a parallel relationship between bleeding severity and mortality.\(^5\) Retroperitoneal bleeding, the most serious of femoral access complications, portends a likelihood of transfusion of up to 75% and a mortality of 10%.\(^6\) Results from the CRUSADE National Quality Improvement Initiative have demonstrated that the need for transfusion is correlated with a higher absolute risk of death in the non-CABG population.\(^7\) These complications are significantly reduced using radial artery access. In a randomized trial comparing femoral and radial cardiac catheterization by interventional cardiologists at a community hospital the rate of vascular complications decreased from 3.71% in the femoral group versus 0.58% in the radial group (p=0.0008).\(^8\) The vascular complications in the radial group were three cases of loss of radial pulse with no resulting forearm or hand ischemia.

The advantages of radial access are especially appealing in the setting of PCI for acute myocardial infarction where there is particularly aggressive use of anti-platelet and anticoagulant therapy for thrombotic lesions. In the hands of experienced transradial operators the door-to-balloon time in an acute myocardial infarction is not prolonged when compared to a transfemoral control group.\(^9\) In one analysis 9.8% of the patients in the transfemoral group had access site complications with four-fifths of those requiring transfusions. In comparison, there was only one access site hematoma in the transradial group. The use of transradial access for acute myocardial infarction PCI is therefore feasible and improves peri-procedural clinical outcomes.

There are challenges posed by the use of transradial access. The inability to access the radial artery is the most common cause of failure of transradial catheterization occurring in 5% of cases in the hands of experienced operators.\(^10\) Various anatomical anomalies also pose challenges to the transradial proceduralist that hinder passage of catheters to the ascending aorta. Another challenge to radial access is the predilection for spasm of the radial artery due to a high density of alpha-1 adrenoreceptors in the vessel media.\(^11\) This is overcome with
adequate sedation to reduce anxiety and with the use of intra-arterial vasodilators after sheath insertion (nitroglycerin and verapamil are routinely used). The introduction of hydrophilic sheath coatings has also contributed to decreased vasospasm and improved patient comfort with sheath insertion and removal. Although vascular bleeding complications are greatly reduced by radial access, radial artery occlusion remains a risk of radial catheterization. Anticoagulation is routinely given intraprocedurally after access is obtained to minimize this risk. Prior to radial catheterization an intact palmar arch is ensured using the Allen's test to minimize the risk of hand ischemia in case of radial artery occlusion.

Since its introduction two decades ago the use of transradial access for cardiac catheterization and intervention has had a slow rate of adoption in the U.S. cardiology community. There have been many reasons for this slow adoption rate including lack of operator experience and training leading to longer procedure times and increased failure rates. At VHVI, we have successfully instituted the transradial technique by aggressive staff training and appropriate addition of new transradial equipment and technologies. Using data from the National Cardiovascular Data Registry (NCDR) database, Rao and colleagues reported an overall prevalence of radial access for percutaneous coronary intervention (PCI) in the United States of 1.32% for the years 2004 through 2007. At Vanderbilt Heart and Vascular Institute (VHVI), during the calendar year 2010, the use of radial access stood at 18.5% of all coronary interventions performed. When compared to data in the NCDR database, our utilization of radial access ranks our institution within the top 5% of all U.S. centers.

As evidenced by recent articles in the lay public, patient awareness and demand will continue to rise for this technique. Consumers will increasingly seek out those centers and interventional cardiologists who are experienced with transradial catheterization. Payers and quality grading organizations may also focus on this technique as a means of limiting complications and reducing costs. Transradial cardiac catheterization is thus an important technique with significant implications for the interventionalist; the patient, the referring physician, and third party payer.

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Figure 1: Data from the NCDR Database showing the prevalence of coronary intervention via the transradial approach in the United States between 2004 and 2007. Current Vanderbilt Heart radial access for coronary intervention stands at 18.5%, which is in the top 5% of all U.S. Centers.

Figure 2: Hemostasis device applied after transradial cardiac catheterization. (Terumo Interventional Systems, Somerset, NJ)
The Radial Approach to Cardiac Catheterization and Intervention

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