

The Journal of *The Heart Institute of Dayton*

An affiliate of Good Samaritan Hospital

Cardiovascular Medicine and Surgery, Research, and Health Policy

Editorials

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of Dayton (JTHID)

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The Journal of The Heart Institute of Dayton (JTHID) supports the sharing of best practices and innovations surrounding the cardiovascular field throughout the region.

The JTHID asks your participation through original contributions, review articles, commentaries and case reports concerning cardiovascular medicine, surgery and health policy.

Join us...

The JTHID welcomes discussions concerning potential submissions and will duly consider all manuscripts submitted. Manuscripts may be presented to the journal's Managing Editor, Joshua L. Lader, at: jllader@shp-dayton.org.



A Journal is Born: The Journal of the Heart Institute of Dayton (JTHID)

Sylvan Lee Weinberg MD, MACC, FESC

On behalf of The Heart Institute of Dayton (THID), an affiliate of Good Samaritan Hospital, it is my great pleasure and privilege to introduce the inaugural issue of The Journal of the Heart Institute Dayton (JTHID). The birth of a journal is always an exciting event, especially when it occurs in a hospital. Sir Francis Bacon, a 16th century English philosopher, statesman, scientist, jurist and author said: "Reading maketh a full man, conference a ready man, and writing an exact man." The JTHID will stimulate and encourage our hospital staff members and its readers, to embrace Lord Bacon's admonition that reading, conference and writing will make them full, ready and exact.

The content of this inaugural issue is emblematic of the role of JTHID. The publication of papers by Drs. Joffe and Broderick, for example, require them to go beyond the challenging work of doing the procedures, to defining and describing exactly what they have done, to disseminate it throughout the area, a task perhaps more time consuming than the procedure

itself. But as Bacon suggests, the act of writing "maketh... an exact Man." Further, the publication in the JTHID of the papers by Ulyot and Bove, based on their presentations at our Distinguished Lecturer series, increases their audience from some 70 to a potential of 2000. Thus does the JTHID pursue its mission of cardiovascular education and prevention programs for physicians, nurses, medical technicians and the public at large. The JTHID encourages its readers to send their critiques and indeed their commentaries and manuscripts for publication.

The Heart Institute of Dayton is a not-for-profit, 501(c)3 organization, created following the May 2008 acquisition of the Dayton Heart Hospital by Good Samaritan Hospital. The JTHID is a controlled circulation publication distributed to over 2000 physicians in greater Dayton and its environs, an area defined by Lima to the north, Richmond, Indiana to the west, Middletown to the south and Springfield to the northeast.

Institute of Dayton and Clinical Professor of Medicine at the Wright State University School of Medicine. Dr. Weinberg founded the first coronary care unit in Ohio at Good Samaritan Hospital in Dayton where he was Director and Chairman of Cardiology, 1966-1999. He directed the Wright State University fellowship program from 1980-1989 and headed a cardiology group practice, until he retired from practice at the end of 1999.

A past president of The American College of Cardiology and The American College of Chest Physicians, Dr. Weinberg was Editor-in-Chief of *Accel*, The American College of Cardiology's international journal on tape of contemporary cardiovascular medicine and surgery from 1985-2000. He is the founding editor of the *American Heart Hospital Journal*, 2002-present. A founding Co-editor of *Heart & Lung* from 1972-1985, and founding editor of *Dayton Medicine*, 1980-present, he has served as an associate editor of the *AMA Archives of Internal Medicine*, the *ACC Review Journal* and on a number of editorial boards, including the *Journal of the American College of Cardiology*, *CHEST*, *Clinical Cardiology*, and *Heart* (formerly *The British Heart Journal*). He has published widely in the medical literature and made more than 230 invited appearances in North America and on five continents overseas.

Clinical Use of Impella 2.5 in High Risk Coronary Intervention

The Dayton Heart and Vascular Hospital at Good Samaritan Experience

C. David Joffe, MD, FACC, FSCAI

Ongoing advances in coronary artery disease treatment have allowed the interventional cardiologist to offer percutaneous coronary angioplasty (PTCA) and stents to more patients. Even patients with poor heart muscle function due to advanced coronary disease can now be treated this way. The safest approach is to support the weak heart muscle with a percutaneous left heart assist device which offers a solution to patients who otherwise are considered untreatable or not surgical candidates.

A novel percutaneous circulatory support device has recently become available for general use outside of clinical trials in the US. The Impella 2.5 (Abiomed, Danvers, Ma.) is a totally percutaneous system which can deliver up to 2.5 liters/min of systemic blood flow and is inserted via a 13 French sheath. The larger Impella 5.0 (Abiomed, Danvers, Ma.) is also available delivering up to 5 liters of circulatory support. This catheter is 21 French at its widest diameter and is therefore typically inserted via a femoral or axillary artery cut-down. This is a case report of an Impella case, as well as a report of our experience with the Impella 2.5

Case Report

A 72 y/o male sustained an extensive myocardial infarction (MI) in 2008. His physicians at an outlying hospital declined invasive workup or intervention due to a history of renal insufficiency and prior stroke. Over the next 15 months, he developed progressive symptoms of systolic heart failure and angina.

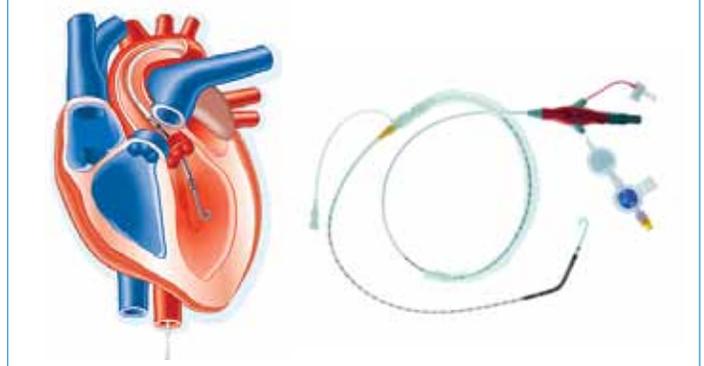
In September 2009, the patient was admitted to the Dayton Heart and Vascular Hospital at Good Samaritan with profound heart failure. Echocardiography revealed severe left ventricular dilatation, major segmental wall motion abnormalities and markedly reduced ejection fraction. He was treated with diuretics, inotropes, and afterload reduction. Despite optimal medical management (OMM), he remained very weak with progressive heart failure and angina.

Diagnostic cardiac catheterization completed in early October 2009 showed profound left ventricular dysfunction with an EF of 10%. Besides extensive multivessel coronary artery occlusive disease, bilateral renal artery stenosis, and moderately severe pulmonary hypertension, he had bilateral iliac occlusive disease and extensive distal peripheral vascular disease. (Fig 1)

Elective supported percutaneous coronary intervention (PCI) was accomplished using Impella 2.5. The details of Impella insertion have been described elsewhere, but briefly, the Impella 2.5 was placed via a 13 French sheath in the left groin. After successful placement in the left ventricle and support initiated with Impella, the extensive coronary intervention and peripheral arterial endovascular procedure were carried out. Four drug-eluting stents in the left main, LAD, ostial circumflex, and right coronary, as well as right renal artery and iliac stents, were placed via the right and left groin.

The Impella was placed via the left femoral artery after initial PTA of the left iliac. The renal procedure and PCI were performed via the right femoral. The Impella catheter

Figure 1 The Impella 2.5



supported the patient for two hours. After a 30-minute period of weaning, the Impella was removed and hemostasis was achieved with two previously placed Perclose devices. Distal pulses were intact, and the patient was followed overnight in the step-down unit.

Discussion

A significant number of patients with impaired left ventricular function and severe coronary disease present a dilemma for the interventional cardiologist. Even slight changes in the function of remaining contractile segments can significantly affect the global myocardial function and can cause precipitous failure in the cath lab during intervention. Referral of these patients to the cardiac surgical service for emergent revascularization is problematic since they often are poor surgical candidates or have been refused surgical intervention. In the past, most patients have been treated with prophylactic IABP therapy, but this has never been shown to have a significant impact in LV function or survival; in fact, with AMI patients there was an increase in bleeding complications and strokes associated with IABP use. (Squaw) Use of circulatory support with CPS enabled longer inflation times in the PTCA era, but the high complication

rates (most notably peripheral vascular) limited adoption of this technique. Burkhoff was unable to show superiority of Tandem Heart (Cardiac Assist, Pittsburg, Pa.) to IABP in high-risk PCI, and there was a very high rate of peripheral vascular complications in this and other series.(Burkhoff, Thiele)

The Impella catheter system (Abiomed, Danvers, Ma) consists of an axial flow pump mounted on a 9 French catheter. The smaller Impella 2.5 is a totally percutaneous system placed via a 13 French sheath and is capable of delivering approximately 2.5 liters/min from the left ventricle through the aortic valve to the ascending aorta. The goal of the therapy is to increase systemic flow, decrease left ventricular diastolic pressure (LVEDP), and increase aortic mean pressure. The effective increase in cardiac output, aortic pressure, and coronary flow has been well documented in the literature. (Remmelink, Sauren). The Impella 2.5 system is placed into the left ventricle via an 0.018" guide wire using a mono-rail technique; this places ventricular assistance in the cath lab entirely within the purview of the interventional cardiologist. The Impella 5.0 LD systems deliver up to 5 liters/min of flow and are designed for direct surgical insertion, also placed via a guide wire, into the femoral artery or ascending aorta, respectively.

The system has been found to be effective in the high-risk PCI patient population with a low rate of adverse events. (Dixon, Henriques). The device has a low overall complication rate, with no aortic valve injuries, no reported infections and no thromboembolic events. (Dixon, Henriques, Maini) Impella use in AMI has also been encouraging with three-year data from the MACH II trial showing a significant increase in the EF over time. (Henriques) Additionally, Maini reported the USpella registry which showed a significant increase in EF following HR-PCI in a group of patients with some of the worst coronary disease ever documented in a contemporary study, with a Syntax score of 39. (Maini) In fact, there are now three patient series that have reported an increase in EF following revascularization during Impella support. (Bruzotta, Dixon, Maini).

The US experience with Impella 2.5 is currently reported in over 1700 cases since its July 2008, general release in the US - 66% belong to the HR-PCI cohort and the other 33% belong to various acute indications such as AMI (15%) and cardiomyopathy (6%) with surgical indications representing only about 9%.(Abiomed Data). Other uses have included hemodynamic support during extensive EP/ablation cases, as well as during or following Balloon Aortic Valvuloplasty (BAV).

At the Dayton Heart and Vascular Hospital at Good Samaritan, we have used the Impella 2.5 system for twelve (12) patients. Nine (9) are still alive. One patient who expired was in his 90's and had presented in cardiogenic shock to the catheterization lab. The Impella was placed in that desperately ill man in an attempt to perform an emergent revascularization. This was accomplished safely, but the patient continued to decompensate and died the following day of profound shock. Another patient who expired was also elderly and presented with critical aortic stenosis, critical left main bifurcation disease, and heart failure. She survived aortic valvuloplasty and left main bifurcation stenting, but died several hours

Figure 2 *The Impella across the aortic valve*



Figure 3 *Pre intervention left and right coronary pre left*

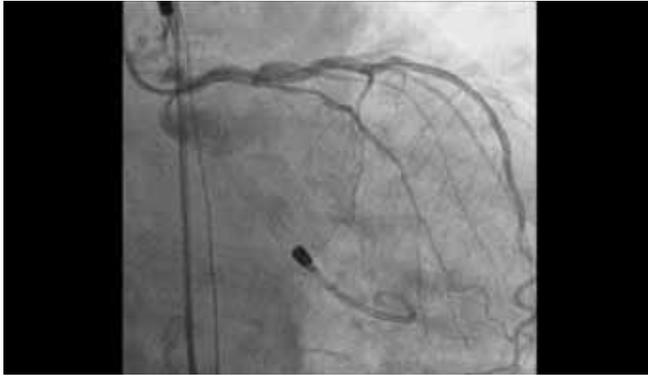


pre right



later. The nine survivors underwent semi-elective Impella implant; all interventions were successfully accomplished, and the device was successfully weaned and explanted. In our experience, the Impella 2.5 allows adequate hemodynamic support, unloading of the left ventricle, and reduces the risk of hemodynamic deterioration during high-risk coronary interventions. We can extend our indications to higher-risk individuals previously turned down for surgical therapy or judged to be at excessively high risk for percutaneous intervention. Impella use is valued as an enabling technology permitting the cardiologist to work with greater care and less fear of hemodynamic decompensation. Utilization of the Impella system both in high-risk intervention cases, as well as for AMI cardiogenic shock patients with continue at The Dayton Heart and Vascular Hospital at Good Samaritan.

Figure 4 Post intervention left and right coronary post left



post right



Figure 5 Pre and post right renal arteriogram renal pre



renal post



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Dr. Joffe is a pioneer in the field of coronary and peripheral angioplasty and maintains an active practice at The Dayton Heart Center. Triple-board-certified in Internal Medicine, Cardiology and Interventional Cardiology, Dr. Joffe is the founder and President of The Heart Institute of Dayton a nonprofit with a commitment to cardiovascular education and improving the quality of cardiovascular health in the region through professional and public education. Dr. Joffe also serves as a Clinical Professor of Medicine at the Boonshoft School of Medicine at Wright State University.

Transradial Cardiac Catheterization and Intervention: Observations on its Place in the Catheterization Laboratory

George T. Broderick, Jr., MD, FACP, FACC

Introduction

The use of the radial artery to achieve vascular access to perform cardiac catheterization and percutaneous coronary intervention is an inherently appealing approach with its potential to improve patient satisfaction and lower bleeding complications. Transradial catheterization has been employed for over twenty years yet it is still not practiced frequently in most catheterization centers in the United States. Currently only one to three percent of coronary catheterizations in the United States are done transradially (1) but many operators are using this approach in the overwhelming majority of their procedures. There is a seemingly strong reticence in the United States for operators to take up the gauntlet of transradial catheterization most likely related to an underestimation of the benefits to patients in its use and an exaggerated concern about the learning curve in acquiring expertise in the technique. Operators who are quite comfortable using the femoral approach and who do not perceive that the approach is associated with an excess of vascular complications in their hands see little reason to take on the “burden” of learning the technique, mastering the anatomic differences inherent in transradial access and becoming comfortable with its use. Fortunately the learning curve for experienced operators is not steep and with persistence and dedication operators can quickly become adept in the transradial technique. Transradial catheterization and percutaneous intervention have definite advantages for patient comfort and satisfaction in addition to easing nursing and post procedure care as well as lowering vascular complications. There are pitfalls with the technique such as difficulty in gaining access through tortuous vascular anatomy and difficulties in adequate guide support and coronary cannulation but with increasing operator experience these problems can be minimized. Establishing a successful transradial cardiac catheterization program can be a boon for patients and staff as well as the operator. The safety of this approach has been consistently demonstrated compared to femoral access and this benefit as well as patient convenience is driving the push toward transradial access.

Patient Selection and Access

Though experienced transradial operators can successfully perform most coronary interventional procedures initially patient selection is critical in facilitating the learning curve and early success in learning the technique. Initial selected patients should be stable patients without acute coronary syndromes who are less than seventy years of age with an easily palpable radial pulse and are not small in stature.

Elderly patients especially with a long history of hypertension can have tortuous subclavian systems that make entrance into the ascending aorta and cannulation of the coronary ostia problematic. Small, thin elderly patients in general will have smaller radial arteries that make initial access more challenging. Middle aged larger males with excellent radial pulses make the ideal candidate for initial radial training. It is also prudent to perform initial percutaneous interventional procedures on more straight forward anatomic situations and avoid chronic occlusions, complex bifurcations and cases in which guide support is difficult to obtain.

Absence of a palpable radial pulse is a contraindication to transradial catheterization. The Modified Allen’s Test is used to establish the presence of a well functioning collateral arch system in the hand between the radial and ulnar arteries (4). While palpating and then obliterating both the radial and ulnar pulses the patient clenches his fist until skin blanching occurs and the with the release of ulnar pressure the time to normal skin color in the palm returning is measured which is normally within seven seconds. Some laboratories also use a modified technique using SpO2 pulse oximetry with finger plethysmography. Practically the Modified Allen’s Test is a fast and accurate technique to establish an appropriate collateral circulation in the hand to be able to proceed with transradial catheterization.

The radial artery is prone to vasospasm due to its high level of alpha-1 adrenoceptors (2). Adequate sedation of the patient seems to lower the chance of radial artery spasm. Radial artery spasm can occur three to twenty percent of the time but is markedly reduced with direct injection after arterial access is obtained by vasodilator cocktails. Typically a cocktail of three thousand units of heparin, one thousand five hundred ucg of verapamil and one hundred and twenty ucg of nitroglycerin are injected through the inserted sheath. Some operators inject up to two to three mg of verapamil. This injection lowers the chance of spasm and radial artery occlusion. Radial artery occlusion is the most common complication of radial artery access and may occur between three and nine percent of the time (3). Heparin either delivered intravenously or through the arterial sheath lowers the chance of radial artery occlusion. In general radial artery occlusion is well tolerated. Repeat access can be frequently obtained in the same radial artery during the same admission in the rare chance of a staged procedure if the Modified Allen’s Test is normal and there is a persistent good radial pulse.

The right radial artery is normally used for access due to operator convenience with the typical catheterization table set up. The left radial artery can be used but often can be an

inconvenience for operator and patient given the need for adduction of the left arm across the patient's torso. This can be difficult in patients who are overweight. Surgeons who use radial conduits for coronary bypass procedures generally will use the non dominant hand and this requirement needs to be taken into consideration during planning the procedure.

Our laboratory has found that placing a rotating arm board under the shoulder extending out under the arm facilitates ease of movement and placement of the radial sheath. The arm and wrist can be conveniently abducted to allow the operator to easily obtain radial access and then allowing adduction of the arm to then allow for the procedure to continue. We also have found that a two foot by three foot Plexiglas board placed under the patient and extending out toward the operator from the table allows enough room for working with the diagnostic and interventional equipment and is more convenient for the operator and technologist.

Various catheter companies now make convenient radial sheath kits in five and six French sizes. These kits come with hydrophilic coated sheaths with more graduated introducers to limit radial artery spasm and facilitate introduction, various micropuncture needles or small gauge intravenous catheters that are used to puncture the radial artery to gain initial access and an 0.018 inch guide wire (Figure 1). With the wrist in the hyper extended position a very small amount of lidocaine is injected at the radial pulse site. It is important to attempt cannulation one to two centimeters proximal to the flexor crease and radial styloid. Using the small gauge intravenous catheter in the kit most operators will puncture through the anterior to the posterior wall of the radial artery, remove the needle and slowly pull back the plastic catheter until vigorous backflow of blood is seen (Figures 2,3). Then the 0.018 inch guide wire is inserted. The guide wire should be rotated while being inserted to avoid the occasional inadvertent insertion into a side branch which rarely can lead to a small perforation. A five or six French sheath is then inserted over the wire. The vasodilator cocktail is then given intra-arterially. The patient's arm is then placed in the adducted position and the operator inserts a diagnostic catheter over a 0.035 inch guide wire and slowly advances the wire and catheter into the subclavian artery and into the ascending aorta (Figures 4,5).

Right heart venous catheterization can concomitantly be performed simultaneously through the cephalic or brachial vein or one of their branches using the identical five French guide wire kit used for radial access. Numerous companies supply five French flow directed balloon catheters that can be used for right heart catheterization. Judicious use of small injections of intravenous contrast oftentimes helps in passage of catheters through the peripheral venous system to the right heart. Patients can be fully evaluated for valvular disease such as aortic stenosis or pulmonary hypertension through arm access at the same time as the left heart is evaluated transradially. This approach can be especially gratifying in elderly patients with aortic stenosis and severe peripheral vascular disease.

Post procedure the sheath is removed in the catheterization laboratory and most operators now use various compression devices such as the Terumo TR Band to facilitate sheath removal and hemostasis (Figures 6,7,8). Patients can literally walk out of the laboratory outside of sedation considerations. The compression devices are removed in one to two hours depending on whether an intervention was performed and they have markedly contributed to patient and nursing satisfaction. Patients who have had coronary procedures from both the femoral and radial approaches overwhelmingly prefer the radial approach due to its advantageous effects on bleeding, access site discomfort, minimal back and leg pain and ambulation.

Peripheral Anatomic Considerations

Once radial access is obtained placement of coronary catheters over a 0.035 inch guide wire through the radial, brachial, axillary and subclavian arteries into the ascending aorta overwhelmingly goes smoothly. Certain anatomic considerations and anomalies however can make gaining access into the ascending aorta problematic. Anatomic variations of the radial and axillary arteries are not uncommon (5) and can contribute to unsuccessful radial catheterization. Torturous radial arteries, radial artery spasm, rare radial artery atherosclerosis, radioulnar loops and torturous subclavian systems all can contribute to difficulty in accessing the ascending aorta and ultimately the coronary tree.

Radioulnar loops can occur in up to two percent of patients (6) and occur as a loop near the site where the radial joins the ulnar artery to form the brachial artery. The loop can be quite problematic and usually a 0.035 inch guide wire will not pass through it. It is important for the operator to always slowly advance the initial guide wire placement through the radial and brachial system to avoid damaging and causing perforations in small side branches or radioulnar loops. Frequent use of small dye injections with angiography of areas where the wire cannot pass easily will allow for passage of 300 cm 0.014 inch PTCA guide wires such as the Runthrough or BMW wires which usually can be advanced easily through radioulnar loops or tortuosity allowing subsequent passage of coronary catheters. Typically the radioulnar loop will straighten out and further coronary angiography and intervention is easily performed.

The subclavian artery can be torturous especially in elderly hypertensive females. Having the patient take a breath usually straightens out the subclavian/innominate artery junction descending into the ascending aorta and allows for its access. Care must be taken in not pushing the wire or catheter aggressively near the innominate/aortic junction as rarely dissections and embolization have occurred. Once ascending aorta access has been obtained all catheters should be exchanged from the aorta with a 260 cm 0.035 inch exchange wire to avoid trauma or spasm in the radial and brachial system. Surprisingly after obtaining aortic access through a torturous radial system or radioulnar loop intervention can still easily be performed due to the ease and

straightening out of the radial arterial system. It is important to use exchange wires when removing angulated catheters such as a pigtail catheter or LIMA catheter as these catheters can cause damage to the radial system during abrupt removal.

Diagnostic and Interventional Catheters

Most operators will initially use a five French sheath and catheters for initial angiography. The Jacky catheter from Terumo has a double angle and side holes which can be used for left ventriculography, ascending aortography as well as coronary angiography allowing the operator to use one catheter for the diagnostic procedure. The catheter can be a little tough to manipulate at times especially given the five French size and while learning the operator may use a typical Judkins left 3.5 or 3.0 catheter and a Judkins right 4.0. Over time operators will come to have used most of the diagnostic catheters one normally uses from the femoral system including EBU, XB and Amplatz designs. Cannulating the coronary ostia is more challenging using the radial approach but the operator rapidly becomes experienced in the nuances of engaging the ostia. Occasionally inadequate engagement necessitates subsequent femoral access to complete the procedure but this situation markedly diminishes with continued experience.

Percutaneous intervention typically is now performed through six French systems and not uncommonly after diagnostic catheterization with five French system the sheaths are exchanged for a six French system. Given the technical advances in five French interventional guides and advanced delivery options with newer stent platforms many straightforward interventional cases can be performed with five French guides. Operators need to evaluate closely issues of guide support, coronary calcification and tortuosity and angulation before proceeding with five French systems for intervention from the radial site. If there is any question concerning guide support or device delivery a six French system should be used. Operators have performed quite advanced interventional procedures transradially including directional rotablation, complex bifurcation procedures, left main interventions and chronic occlusions (7,8). Rarely seven French systems can be used in larger patients but in general this is avoided. It is not uncommon during the learning curve for operators to perform diagnostic angiography transradially and find technical and anatomic characteristics of the coronary anatomy which suggests a concomitant femoral approach for intervention is warranted. These situations markedly disappear with increasing operator clinical transradial experience.

As the operator gains increasing experience progressively complex procedures can be attempted. It is imperative however for the operator to always be aware of the balance between intervening in a complex anatomic situation from a transradial versus femoral approach and making sure he or she is comfortable with the decision to intervene from the site which is safest for the patient while also ensuring a successful procedure.

Vascular Complications: Femoral vs. Radial

Though transradial catheterization and coronary intervention are associated with increased rates of patient satisfaction and convenience the main importance in the use of the radial access site is the significant reduction in vascular complications that can be obtained with its use. Recent interventional clinical trials over the last decade have consistently shown the importance of bleeding and vascular complications to overall clinical morbidity and mortality. The importance of bleeding complications is a major focus of interpretation currently of clinical interventional trials and the continued aggressive approach to limiting these important complications highlights the distinct advantage transradial percutaneous intervention offers to patients.

The radial artery is easily compressible as it sits just anterior to the radius bone. Bleeding and vascular complications are significantly reduced using the transradial approach. Several observational and randomized trials have demonstrated the superiority of transradial over femoral access in vascular and bleeding complications. Brueck and colleagues performed a randomized trial of patients undergoing cardiac catheterization and coronary interventions and looked at outcomes and vascular complications. 1,024 patients were randomized to either approach. Vascular complications were higher in the femoral access group (3.71%) versus the transradial approach (0.58%; $p=0.0008$) (9). Vascular complications are particularly dangerous for elderly patients and the prospective OCTOPLUS study reported on octogenarians undergoing cardiac catheterization and intervention via either the femoral or radial approach (10). Patients were randomized to the femoral approach ($n=185$) versus the radial approach ($n=192$). By intention to treat analysis the incidence of vascular complications was significantly less in the radial group (1.6% vs. 6.5%; $p=0.03$).

The persistent and significant reductions in bleeding and vascular complications alone should be a critical driver in having interventional cardiologists strongly consider using the transradial access technique. One difficulty may be that most operators do not perceive that these vascular complication data may relate to their anecdotal clinical experience. Operators may also conclude that the improvement in vascular complications is not significant enough that the extra effort in learning transradial intervention would overall affect their clinical outcomes. More education by the cardiology community is needed to improve patient access to this safer approach to coronary intervention.

Transradial Pitfalls and Complications

Transradial cardiac catheterization and intervention are not without limitations. Though patient satisfaction is higher, bleeding and vascular complications are lower and length of stay and nursing satisfaction is higher there can be problems with the technique. The procedure can be associated with a higher intravenous contrast use and at times a higher use of radiation and fluoroscopy times. Success rates are generally slightly lower than with transfemoral access though this varies markedly with operator experience. This slight variation in success rates versus the two vascular approaches

is probably the major reason operators are reticent about becoming radialists. Lower volume operators probably do not wish to devote the time to learn a new method of vascular access with its attendant difficulties compared to the ease of transfemoral access. Rarely vascular complications such as arm hematomas and compartment syndromes can occur, usually from aggressive wire advancement causing perforation of a radial or brachial artery or one of their side branches. This is a rare complication reported to have an incidence of 0.4% (11) though rarely it can be hypothesized to be caused by diffuse radial artery spasm. Rare sterile or infected abscesses have been reported at the site of radial sheath removal.

Conclusion

Transradial cardiac catheterization and coronary intervention has been in use for over twenty years and is associated with improved patient satisfaction, shorter time to patient ambulation, easier nursing care and lower bleeding and vascular complications compared to femoral access. The use of transradial access by operators in the United States is still very low though this will change with increased physician and patient education and awareness of the distinct advantages of transradial access. Establishing a transradial program or becoming a radialist requires commitment and dedication on the part of the cardiac catheterization laboratory administrators, staff and physicians but the advantages pay off in the end in terms of the procedures numerous advantages. The use of transradial cardiac catheterization and intervention will continue to increase in the United States and internationally as physicians and patients become more aware of the benefits it brings.

Article reprinted with permission from the American Heart Hospital Journal (AHHJ). Dr. Broderick is board-certified by the National Board of Medical Examiners and the American Board of Internal Medicine with subspecialty certification in Cardiovascular Disease. He is the Medical Director of Cardiology Services at the Dayton Heart & Vascular Hospital at Good Samaritan.

Technology Assessment is the Key to Health Care Reform

Daniel J. Ulliyot, MD, MACC

Medical Technology

Americans love technology, especially new medical technology. The cliché “America has the best health care in the world,” really means that American health care uses the most advanced technology to an extent surpassing any other health care delivery system in the developed world. Our federal and state government programs in biomedical research, our universities and affiliated medical schools, and our vast medical/industrial complex including our pharmaceutical and device manufacturing companies, produce thousands of new technologies each year. The National Institutes of Health (NIH) is the primary agency of the United States government responsible for biomedical and health-related research. As of 2003, the NIH was responsible for 28 percent—about US \$26.4 billion—of the total biomedical research funding spent annually in the U.S., with most of the rest coming from industry.

This supremacy in the development, dissemination and clinical application of technology is also the reason our per capita expenditure on health care exceeds that of other “first-world” countries by a factor of two or more. For those with rare afflictions or who have conditions requiring high-tech, sophisticated diagnostic and/or therapeutic interventions (and if one is wealthy or happens to enjoy good health insurance coverage), America is the place to be.

But does this bounty of technology mean Americans enjoy better health—or medical care—than the rest of the world? The fact is that we are not getting our money’s worth. While our per capita spending exceeds that of other developed nations, we rank well below other “first world” countries in measures of public health such as life expectancy, infant mortality, maternal mortality and others.

At the heart of this dilemma is the distinctly American love affair with technology. Technology in health is defined broadly to include drugs, devices, procedures, and organized care such as chronic disease management systems. “New is better” is powerful psychology for patients who want and need access to the “best.” And, to be sure, the triumph of modern medicine is the adoption of the scientific method and the application of science to medical practice. Much medical technology truly is lifesaving and brings enormous benefits to patients. One has only to consider antibiotics, insulin, blood transfusion, vaccination, heart valves, artificial joints, open heart surgery, cancer screening and chronic disease management systems for heart failure and asthma to name just a few.

Conversely, a great deal of technology is actually of little benefit, often duplicative, and sometimes even harmful. Examples are plentiful: “Me too” pharmaceuticals; drugs such as Vioxx, which after initial introduction, FDA approval,

widespread use and exuberant marketing was withdrawn later as safety issues came to light; devices such as defective heart valves and pacemaker lead systems; and surgical procedures such as carotid sinus denervation for asthma and lobotomy for schizophrenia.

Even technologies which have been shown to be safe and effective for specified indications can be inappropriately applied, either over-used, mis-used (as in some “off-label” use) or under-used. The Wennberg and the Dartmouth group study of documented variation in medical practice points out significant local and regional differences in the use of medical technology, concluding that much medical practice is arbitrary and lacking convincing supportive evidence.

The key—and the success of any effort at health care reform—will be to develop a competent and fair system to evaluate which technologies merit adoption, always balancing benefit and affordability.

Technology Assessment

There is a growing demand for “evidence-based medicine,” i.e. the requirement for rigorous scientific evidence in clinical practice, particularly as innovation has proliferated and the medical armamentarium has become increasingly complex and expensive. There are a number of efforts both public and private to apply rigorous scientific analysis to the assessment of medical technology (Table I).

Table I
Who is Doing Tech Assessment?

Public Sector

- Agency for Healthcare Research and Quality (AHRQ) and its EPCs
- Medicare Evidence Development and Coverage Advisory Committee (MedCAC)
- WA State HTA Program

Private For-Profit

- Hayes, Inc.
- Consulting firms (Lewin, Avalere, Lash Group)

Private Non-Profit

- California Technology Assessment Forum (CTAF)
- California Health Benefits Review Program (CHBRP)
- Blue Cross Blue Shield Association Technology Evaluation Center (BCBSA TEC)
- ECRI Institute
- Institute for Clinical and Economic Review (ICER)
- Center for Medical Technology Policy (CMTTP)

• One such activity is the California Technology Assessment Forum (CTAF), a private, non-profit organization sponsored by The Blue Shield of California Foundation. The CTAF panel of experts consists of approximately 15 voting members including medical and surgical sub-specialists, methodologists, ethicists, and consumer advocates who meet three times a year in public session to evaluate four or five new medical technologies at each session. CTAF employs reviewers who are members of the University of California, San Francisco, medical faculty, and who search the published literature relevant to the topic at hand and prepare a report on the extent to which the published data fulfill the five CTAF criteria (Table II). After considering the reviewer's recommendation, hearing testimony from experts, and full discussion by the Panel, a vote is taken. If the vote affirms that all five criteria are met, the technology is declared "approved" for clinical application for the clinical conditions specified in the studies cited. If CTAF criteria are not met, the technology is said to remain "investigational." It is emphasized at each public meeting that the process is focused on safety and effectiveness and is not for the purpose of making insurance coverage decisions. Nor is cost considered in CTAF's assessments.

Table II
CTAF Assessment Criteria

1. Technology must have final approval of the appropriate regulatory bodies.
(Usually FDA approval)
2. Scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.
(Published evidence published in peer-reviewed journals; RCTs preferred)
3. Technology must improve net health outcomes.
(Beneficial effects must outweigh harmful effects)
4. Technology must be as beneficial as established alternatives.
5. Improvement must be attainable outside investigational settings

Table III lists a sample of topics considered over the past six years, highlighting those approved. The overall percentage of technologies meeting CTAF criteria is just under 30 percent. Failure to meet criteria may mean simply that the data are insufficient to draw conclusions. The technology

may be promising but is in need of further study, not necessarily unsafe, ineffective, or both.

Table III
Miscellaneous CTAF Topics
(2003 – 2008)

- CT Colonoscopy
- *Drug-eluting vs. Bare-metal Coronary Stents*
- Human Papilloma Virus Testing in Cervical Cancer Screening
- Laparoscopic Gastric Banding for Morbid Obesity
- *Cardiac Resynchronization Therapy for Treatment of Heart Failure*
- *Fecal DNA Testing for Colorectal Cancer*
- Cryoblation for Treatment of Breast Fibroadenomas
- *Wireless Capsule Endoscopy in the Evaluation of Established Crohn's Disease*
- Genetic Testing to Guide Initiation of Anti-coagulation with Warfarin
- Robot-assisted Surgery for Radical Prostatectomy
- *Met CTAF criteria*

Health Care Reform

There are three central elements in the current debate about health care reform:

- (1) Increasing access, i.e. providing some degree of insurance coverage to the estimated 61 million Americans who are uninsured (45M) or underinsured (16M),
- (2) Improving the quality of care, i.e. eliminating some of the medical errors leading to death and disability, and promoting "best practices" shown to result in improved patient outcomes, and
- (3) Reducing the cost of care, i.e. "bending the cost curve."

By far the most important of these elements is cost reduction. If we simply increase access to a system of care which is financially unsustainable, we will not have achieved meaningful reform. Also, gaining control of ever-rising health care costs by limiting the use of technologies which are not beneficial or may be harmful will also improve care quality.

Health care is increasingly unaffordable to many Americans, not just the poor. Health care costs are hurting our competitive position in the global economy. Approximately 46 percent of health care expenditures are funded by government, and health care-related entitlements are projected to place a heavy tax burden on future generations. Medicare is projected to become insolvent by 2017.

In 2007 we spent \$2.2 TRILLION on health care, which is 16 percent of GDP and amounts to \$7,420 for every man, woman and child in the United States. Health care costs have risen an average of 2.4 times CPI, and have done so since 1970. What is it that drives medical cost inflation? Health economists all agree that far and away the single most important factor is new medical technology. To be sure, there are also other influences such as incentives to increase the volume of services to maximize income for doctors and hospitals, the insulation of both patients and doctors from the costs of care, the profit incentives for pharmaceutical and device manufacturers and their shareholders, and, not least, the public's insatiable desire for any and all medical care from which they might conceivably benefit, whatever the cost, and especially if perceived as free. "Health care is a right, not a privilege," sums up the sense of entitlement for the ever increasing supply of medical and surgical services, as more and more of everyday life becomes subject to medical intervention.

With the advance of medical science more and more of life has become "medicalized." For example, the inability to conceive was described once as a "barren couple" or "God's will." Now, thanks to scientific advance, this condition can be treated as an "infertility problem" with sperm counts, ovulatory cycles, ex-vivo fertilization, and pharmaceutical manipulation of implantation and gestation. Other examples include the drug treatment of inattention in school children (ADD), erectile dysfunction (ED), depression and anxiety; cosmetic surgery, LASIK surgery to obviate the need for eyeglasses or contact lenses, bariatric surgery for obesity and a variety of surgical interventions to improve performance or duration of participation in athletics.

The point of these diverse examples is to illustrate that because of the ever expanding applications of medical technology to everyday living, the demand for health care is insatiable, infinite, and ultimately unaffordable. How do we begin to pare back our health care expenditures?

Solutions

If technology is the major driver of increasing health care costs, and if the central element of health care reform is cost containment, or, as some have called for: "bending the cost curve" then how we evaluate and use technology is one of the ways, and perhaps the most important way, to achieve this goal.

We need to know: "What works?" In other words how do we know which technologies work? This is an epistemological question taking us into the realm of philosophy. Epistemology is that branch of philosophy dealing with knowledge, i.e. "How do we know what we know?" In medical technology, we need to examine scientific evidence for safety and effectiveness, benefit in terms of patient-centered outcomes (survival, function and quality of life), comparison with existing technologies and whether the technology can be applied outside of research environments. The gold standard for "knowing what we know" about "what works" is the well designed Randomized Controlled Trial (RCT), appropriately

powered statistically to allow inferences to be drawn. The CTAF process is a good example of this kind of technology assessment based on objective data published in the peer-reviewed medical literature.

Technology assessment is not easy or inexpensive. The alternative is the acceptance of technologies based on "clinical experience," which at its best can identify beneficial technologies, but can often be quite wrong, and at worst be subject to the malign influence of the provider's (doctor's or hospital's) reimbursement needs, direct-to-public marketing, and the hopes and yearnings of the afflicted for any benefit, however unlikely, and no matter the cost.

In our present system, where some technologies can cost vast sums and can be initiated by a stroke of the doctor's pen, the idea that the doctor-patient interaction is inviolate is no longer tenable. As physicians we all value professional autonomy, but in order to limit the indiscriminate use of medical technology there must be limitations, perhaps peer pressure, public disclosure, or some measure of coercion such as denying payment for some applications.

Public education is also crucial for cost control. It will require a cultural change to convince consumers that good medical care must be evidence-based. It is useful to reflect on three examples of well accepted technologies which, after wide acceptance in medical practice, were later discredited when subjected to rigorous analysis.

For the public to embrace a culture in which medical practice is evidence-based and understand that this is a path to better

Example 1:

The Cardiac Arrhythmia Suppression Trial (CAST)

Ventricular ectopic beats, so-called PVCs (Premature Ventricular Contractions), are known to be correlated with sudden death following acute myocardial infarction (AMI), and, therefore, it was common clinical practice to suppress PVCs using antiarrhythmic drugs following a heart attack.

However, when this practice was tested in a Randomized Controlled Trial (RCT), surprising conclusions were reached.

Patients within 90 days of an AMI having ECG evidence of ectopic beats were randomized into a treatment arm using the antiarrhythmic agents Encainide and Flecainide, and a placebo arm. The trial began enrolling patients in 1987 and was stopped prematurely, because patients in the treatment arm had increased mortality and a greater number of non-fatal cardiac arrests than the placebo group. The data showed that ectopic beat suppression not only failed to lower mortality, but actually increased it, and so this widely accepted practice was abandoned.

Example 2:

Bone Marrow Transplantation for Breast Cancer

Nobel prize-winning work in the 1960s and 1970s showed that leukemia could be cured with high-dose chemotherapy and high-dose radiation, and patients could survive this treatment by the use of autologous bone marrow transplantation, i.e. by removing the patient's bone marrow before the highly toxic chemo and X-ray therapy was given, and returning the bone marrow after the therapy was completed.

This experience suggested a similar approach for solid tumors such as breast cancer. Based on early reports of tumor regression (an intermediate outcome), high dose chemotherapy and autologous bone marrow transplantation for breast cancer became widely accepted and led to a proliferation of autologous bone marrow treatment centers for breast cancer. Between 1985 and 1998 an estimated 30,000 women were treated in these centers at a cost of millions of dollars, many treatment-related side effects, and a mortality of 3 percent to 15 percent.

Ultimately, and against great opposition, several RCTs were conducted comparing standard chemotherapy against high-dose chemotherapy and autologous bone marrow transplantation. All RCTs failed to show benefit for the more complicated and expensive treatment, and the discredited technology was subsequently abandoned.

Example 3:

Hormone Replacement Therapy (HRT) in Women to Reduce Risk of Heart Disease (Women's Health Initiative)

Based on the later onset of heart disease in women compared to men, it was thought that HRT in post-menopausal women would prevent or reduce heart disease. Based on this entirely plausible hypothesis an estimated 6 million women were prescribed Estrogen and Progestin for this and other reasons in the United States.

This hypothesis was tested in the Women's Health Initiative (WHI), a study of 16,000 women ages 50 – 59, half randomized to a regimen of Estrogen and Progestin and half to placebo. The study was planned to continue until 2005, but was stopped in 2002 because the women in the treatment segment had increased heart disease, breast cancer, stroke, and pulmonary embolism compared to the placebo segment.

and more affordable health care will require adroit political and scientific leadership. This is admittedly a tall order, but polls showing a large majority of Americans are in favor of health care reform, suggest the cultural change is possible. Comparative effectiveness studies, properly done, that look at what works (safety and effectiveness), for whom and under what circumstances (appropriateness), and at what price (cost-effectiveness) are the path to genuine health care reform.

Health care legislation needs to emphasize cost containment, which, as I have argued, begins with acknowledging that technology assessment can lead us out of our upward spiral of health care costs by limiting the indiscriminate use of technology, the principal driver of medical cost inflation. This sounds like rationing, the dreaded "R-word," which it surely is. However, it is rationing in the sense of limiting costly technologies which are neither beneficial nor harmless, and those whose cost vastly exceeds benefit. An example is the drug Tarceva, which costs about \$3,500 a month and was approved by the FDA as a treatment for pancreatic cancer because it improved survival by 12 days.

The legislation and resulting policies and structures to accomplish health care reform along the lines I am suggesting are beginning to take shape. \$1.1 billion has been allocated for Comparative Effectiveness Research (CER) as part of the American Recovery and Reinvestment Act (ARRA) of 2009, the so-called stimulus package. And much thought is being given to a national forum modeled on the National Institute for Clinical Excellence (NICE), a new agency in the British National Health Service (NHS), which has already produced reports on some 250 medical technologies and provides "advice" on how these should be used in the NHS. NICE has been in existence for a decade, has been accepted by the British people and has stimulated similar efforts in other countries to offer technology assessment and cost-effectiveness determinations by an agency which is independent, transparent and evidence-based. Everyone agrees that America must constrain health care costs, and has the technical expertise to create a national forum to evaluate new medical technologies competently and fairly. We simply cannot keep up our romance with technology, paying whatever providers and manufacturers demand for their services and products. The questions remain: Do we have the political will to limit ourselves? How much health care can we afford?

Editor's comment

Dr. Ulliyot is a cardio-vascular and thoracic surgeon and Professor of Surgery at the University of California, San Francisco, now retired, where he engaged in research, teaching, and clinical practice in a surgical sub-specialty noted for its applications of sophisticated, new medical technology. He is Vice-Chair of the California Technology Assessment Forum (CTAF), a panel which examines new medical technology in a series of three public meetings held each year in California and publishes its assessments on its web site (www.CTAF.org) and in scholarly journals. Dr. Ulliyot is a Past President of the American College of Cardiology and of the Western Thoracic Surgical Association.

Using Modern Communications for Managing Chronic Heart Disease

Alfred A. Bove, MD, PhD, FACC, MACC

Episodic care for patients with chronic diseases such as heart failure, stable angina, diabetes and others is costly and inefficient. Such an episodic care approach also risks deteriorating health as the patient is subjected to recurrent acute exacerbations of their illness that often require heroic therapies, while a system of continuous surveillance with frequent small changes in care prevents acute recurrences.

Management of the presymptomatic phase of heart disease (hypertension, hyperlipidemia) is best done using a patient centered approach that incorporates patient participation, improved health literacy and monitoring of patient status through frequent communication between patient and health care provider. Nurse management has proven effective in improving diabetes (1), hyperlipidemia (2) and hypertension (3). Considering that the prevalence of these disorders is increasing disproportionately to the number of physicians and nurses, information technology could provide a solution for maintaining or improving clinical outcomes, while containing costs.

Telemedicine System

We have used an Internet-based telemedicine system to manage heart failure and cardiovascular disease risk. The Telemedicine system (InSight Telehealth Systems, LLC, Valley Forge, Pa) is a disease-management interactive health surveillance system comprised of a secure Internet server and a database. Details of the Telemedicine system have been described in previous publications (6,7). This system

provides Internet access to a personal health record focused on cardiovascular disease. The server contains the personal health record database linked to a browser interface through secure firewalls. This arrangement allows patients to send data directly to their care provider via the Internet. Patient health information and the communication transactions are stored in the database. The web site is divided into a patient domain, and a provider domain. Each requires a logon ID and password. This system provides HIPAA compliant 128 bit encryption with a secure socket layer and a public key infrastructure so that medical information is safely transmitted via the Internet.

Patients with increased risk for cardiovascular disease (CVD) may be unaware of their risk if hyperlipidemia or hypertension are undetected, as these patients are often asymptomatic. These patients benefit from a telemedicine system for tracking their risk while asymptomatic and gain improved health by avoiding the long term effects of high CVD risk. Although cardiovascular disease continues to be a significant cause of morbidity and mortality in the United States, recent data have demonstrated a significant reduction in CVD mortality in part, related to more aggressive management of modifiable CVD risk factors (12). While mortality from CVD is diminishing, several populations have not shared in this reduction. In particular, ethnic minorities and medically underserved populations are at increased CVD risk due to a high prevalence of obesity with accompanying glucose intolerance, hyperlipidemia, and hypertension (13). Yet in underserved populations, lack of risk assessment and subsequent intervention allows these conditions to persist until an actual cardiovascular event occurs (heart attack, new angina, sudden death or stroke).

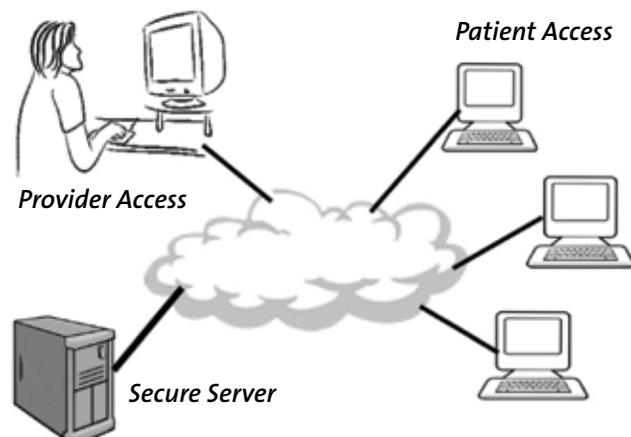
Management of the presymptomatic phase of these disorders is best done using a patient centered approach that incorporates patient participation, improved health literacy and monitoring of patient status through frequent communication between patient and health care provider.

In a study of asymptomatic subjects with high CVD risk, we compared a nurse managed CVD risk reduction program to a nurse management system augmented with telemedicine communication. The telemedicine system allowed subjects living in urban and rural medically underserved communities to report their weight, blood pressure, and physical activity, and receive frequent feedback regarding CVD risk management. We focused on blood lipid and blood pressure management as these involve both practice and patient participation to achieve treatment goals.

We studied 465 patients with a 10% or greater 10-year Framingham risk of CVD (14) who were randomized to nurse management or nurse management plus telemedicine

Figure 1 Schematic of the Internet system used for patient communication. From ref. 7.

Internet-Based Chronic Disease Management
Heart Failure Disease Management
Cardiovascular Disease Risk Reduction



communication. The patients were provided resources for measuring blood pressure, weight and daily activity at home, and were followed for 1-year with the primary end-point being a 5% reduction in their 10-year CVD risk.

Nurse Management

Nurse management involved office encounters with our research nurses at 4 month intervals for 1-year. All subjects were provided a digital sphygmomanometer, a scale if needed, and a pedometer to count their steps per day. Subjects were instructed to record their data (weight, blood pressure, steps/day, and cigarettes/day) at least weekly and enter the data in a logbook, which was reviewed quarterly during a clinic visit with a research nurse. Subjects received education and counseling regarding healthy life-style behaviors (blood pressure goals, weight loss, diet, smoking cessation, physical activity) at baseline and at each clinical encounter.

Telemedicine

Subjects in the Telemedicine group were provided with the nurse management program described above. In addition, each subject was provided with a login name and password to gain access to the secure Internet based Telemedicine system and received instructions on how to access and use the Telemedicine system. Laboratory data and medications were entered into the telemedicine system by a research nurse, and were accessible to the subject via the Internet.

To increase computer access for subjects in the telemedicine group, we identified community centers and libraries where Internet access was available.

Both nurse management and Telemedicine communication proved to be successful in reducing overall CVD risk. Communication between subjects and the research nurses in both groups provided the needed support to improve CVD risk. The subjects were provided with their individual lipids and blood pressure data and encouraged to discuss their CVD status with their physicians.

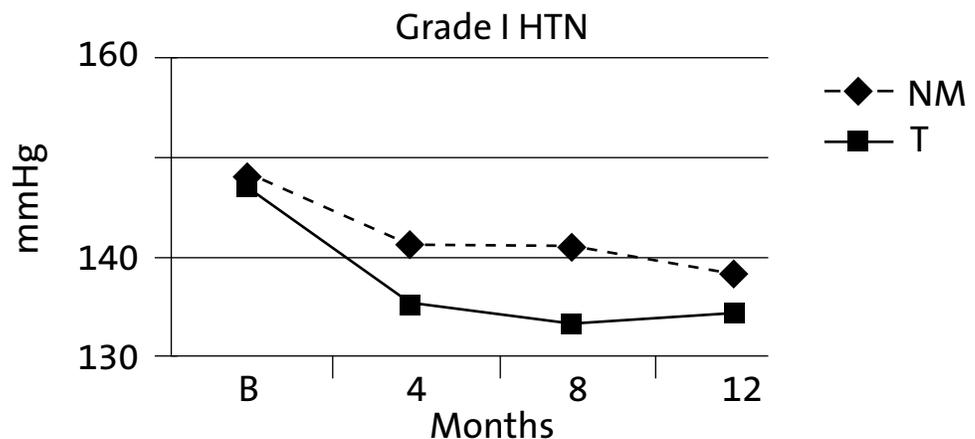
Because we expected a proportion of the subjects to reach goal in the two groups, we separated the total cohort into those who reached the goal of $\geq 5\%$ reduction in Framingham score and those who did not. 112 (28.6%) subjects achieved an improvement of 5% or more in their Framingham score. Table 1 shows the initial and final Framingham scores for the subjects who reached the goal of 5% or greater reduction and those who did not. Improvements in score for both groups was significant at $p < 0.001$. There were no differences in demographics between those who reached goal and those who did not. Those who reached goal had significantly higher initial risk scores than those who did not reach goal.

There were no differences in baseline score or in the final score when comparing nurse managed subjects and telemedicine subjects. The high baseline score was the main distinguishing feature of the group who reached goal.

	Nurse Managed		Telemedicine	
	baseline	final	baseline	final
Goal reached	23.5 \pm 10.7	13.2 \pm 8.1	23.8 \pm 13.3	13.9 \pm 9.5
Goal not reached	15.2 \pm 7.7	16.0 \pm 9.7	15.3 \pm 8.1	15.4 \pm 9.3

Table 1 Framingham risk score in patients with increased CVD risk who achieve at least a 5% reduction in score compared to those who did not reach goal after one year. Both Nurse management and telemedicine resulted in significant reductions in risk.

Figure 3 Changes over one year in blood pressure for patients with grade I hypertension (Systolic BP ≤ 140 mmHg). NM - Nurse management alone, T - NM plus Telemedicine. Difference between curves is significant ($P=0.037$)



The greatest improvement in blood pressure occurred in the first 4 months of the study, and these improvements were sustained throughout the 1-year study period (figure 3). The data suggest that Telemedicine may be useful for managing grade I hypertension, and indicate that patients with high CVD risk scores can lower risk through an education and surveillance system.

A system without video monitoring would cost even less.

Conclusions

Chronic heart disease is increasing in frequency as the population of the United States and other countries becomes older, and improvements in therapy allow patients with chronic heart disease to survive longer with chronic cardiac conditions. Therapy of chronic heart disorders requires frequent surveillance. The use of Internet communication methods shows promise in allowing frequent access by patients to their providers without the need for frequent office visits or telephone calls between providers and their patients. The concept of the patient centered medical home is an ideal basis for use of such communication systems.

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Dayton Heart & Vascular Hospital at Good Samaritan: Cardiac Service Line Quality Process Initiatives

Jeffrey K. Hoffman MD, MPH, Marigene G. Hartker MD, MPH, Jason Jankowiak MBA, MHA

The landscape of medicine has changed. Increasingly, hospitals realize that providing quality of care which is safe, efficient, effective, timely, equitable and patient-centered through use of evidence-based process improvement optimizes patient care. Good Samaritan Hospital has had a collaborative effort with the consulting arm of Healthgrades (HG) for several years to proactively work on opportunities to improve patient outcomes.

This effort was accelerated with the impending merger of Dayton Heart Hospital (DHH) and Good Samaritan Hospital (GSH). GSH administration perceived not only the opportunity to provide a high quality cardiovascular program in the region but as well, the ability to leverage new processes that would define what the best of healthcare would be in Ohio.

The initial analysis was done by HG focused on anomalies in internal, American College of Cardiology (ACC), Society for Thoracic Surgeons (STS) and publically reported (Medicare) data. From there an in-depth chart review was done as part of the root cause analysis. Finally, a gap evaluation focused on areas where improvement would gain a maximum reduction in mortality measures. With this analysis, HG made evidence-based, proven recommendations on process improvement initiatives. As a result, the relationship with HG was expanded not only to encompass the integration of the programs but also to steer the organization toward the goal of being a “5-Star” hospital cardiovascular care delivery.

As part of the reorganization new positions were created within the cardiovascular section. Rich Gulling, BS Pharm, MBA, became the Director, Cardiovascular Quality and Clinical Research position. Jeffrey Hoffman MD, MPH, a retired cardiovascular surgeon, filled the role of Medical Director, Cardiovascular Quality at Dayton Heart and Vascular Hospital (DHVH).

Workgroups utilizing physician leaders as well as clinical staff addressed defined opportunities for improvement. Each group was tasked to create a process of improvement by defining necessary changes, instituting a new process and evaluating how well those changes improved outcomes. One example of a process improvement measure was developing physician evaluation and feedback on a regular basis. Ultimately physicians desire superior outcomes for their patient so showing individual outcomes drives physician and staff change.

A first step was to obtain uniform understanding of the how the organization is measured and the recent data results. The cardiac service line is measured in many different ways. Data is submitted to STS, ACC, Centers for Medicare and Medicaid (CMS), Greater Dayton Area Hospital Association (GDAHA), and multiple insurers. These organizations then rank our outcomes. Variations in data exist because of

differing definitions. As our second step, we created a dashboard of relevant data pulled from all these different sources important to our physicians and the hospital. Our data was compared to best practice benchmarks. Our own performance was also risk adjusted and compared to expected results (observed/expected). Once populated, the next step became dissemination of this data. The dashboard was presented to physicians at section meeting and M&M. It has also been shared with the nursing staff in DHVH. Our colleagues in anesthesia, pulmonary and renal medicine who participate in the care of the patients have also had an opportunity to review this dashboard.

This process was taken further when individual physician scorecards were also created. This allowed the physician to see their performance in relation to their peers within the organization. Each physician received a confidential packet with section dashboard, individual dashboard, and definitions. This process will be repeated every six months as the data is updated.

With the success of the physician scorecards, this process will be repeated for the endovascular interventions and for the Electro-Physiology (EP) lab. These will be shared with physicians and staff on a routine schedule.

Another example of a process improvement implemented by HG was a risk stratification system to (a) identify and optimize the high-risk patient and (b) select those patients who would most benefit from a procedure. HG provided two evidence based risk stratification tools for discussion: the Euroscore and the Mayo Score. These scores represent a way to assess patient risk for procedures based on objective criteria. The Euroscore, used for surgical procedures, has been utilized and validated in Europe and across the STS database in extensive studies. Multiple patient factors and comorbidities elements are added together or scored via a logistic regression pre-procedure to create a score. Because the Euroscore does not determine what is considered high, intermediate and low risk, a small in-hospital study was done on one hundred patients retrospectively to determine what the definitions of “high”, “intermediate” and “low risk” would be.

The Mayo score considers patient comorbidities to predict mortality and major adverse cardiac events (MACE) complications from a percutaneous cardiac intervention in the cath lab. Initially, our patients were scored on paper by the catherization lab staff in the cath lab preprocedure. All patients undergoing an elective catheterization had a Euroscore and Mayo score done pre-catheterization. Further, the scores are part of the “time out” process in the cath lab so that the physician can be aware of the risks for the patient before the procedure. The scoring is available for surgical consultant during the consultation process.

Scores can be done electronically in the EPIC© system and are available to populate lists, consults etc, thus allowing other subspecialties (e.g. anesthesia, renal and pulmonary medicine) a common understanding of a patient's risk profile. The use of EPIC also enables us to track and trend outcomes as they relate to pre-procedural risk, not only for the cardiac section as a whole, but for individual physicians as well. This reporting ability becomes a powerful tool in assessing hospital and physician performance and providing meaningful feedback.

Our goal is to further enhance the patient assessment to improve outcomes. We have emphasized to physicians that this is only one part of physician judgment, and should be viewed as an extra tool in the physician's arsenal of information. It is not used to eliminate procedural choice for physicians or patients but may add some additional certainty to physician decision making

Finally, a revitalized Mortality and Morbidity (M&M) meeting was established. This is held the 4th Thursday of the month at 7:00 AM and was created as multispecialty meeting for cardiology, cardiac surgery, other involved subspecialties and integral members of the staff who care for cardiac patients. The goal is to provide a systematic, retrospective evaluation of patient mortalities and complications. The cases are presented by the facilitator, Dr. Hoffman. Each month two cases are generally reviewed. An integral part of this process is the risk assessment by Euro and Mayo scores which are reviewed in detail for each case and provide a foundation upon which the discussion can build. As well, we have also presented interesting cases which highlight unusual teaching opportunities or new technology.

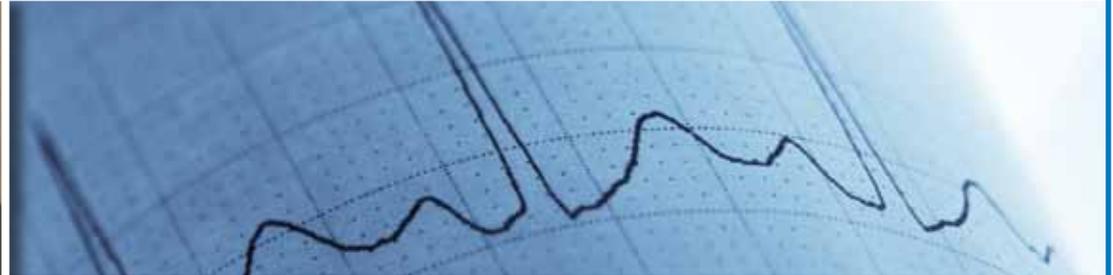
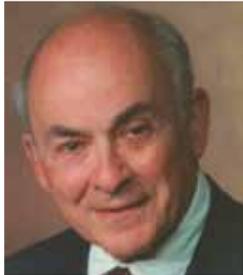
The focus is both on intra-op/intraprocedure care and post-procedure care with the end-goal being specific clinical suggestions for process improvement by providing frank open discussion for many collaborative opinions as to what could have been done differently to achieve a better outcome. When process issues are identified, administration and physician leadership have quickly addressed these problems and instituted solutions that have benefited patient care in a material way. Guidelines were established to promote collegial discussion allowing for accountability without finger pointing. Because of this, the discussions in this meeting have been stimulating with excellent points consistently made. It is fascinating how many divergent and valuable issues can come from this type of discussion. The M&M has also served as an excellent forum for presentation of the dashboard and other vital quality statistics for review.

This article has focused on three new innovative techniques we have adopted at GSH DHVH to enhance our ability to provide superior care to our patients. This is by no means an exhaustive list of our accomplishments but begins to focus the process. The goal is to improve outcomes through a collaborative effort of our physicians and staff. In order to do this we have provided tools to both measure and modify process and outcomes.

Awareness that public reporting will be providing greater transparency, to the government, insurers and patients has become a reality at Good Samaritan. The hospital and the physicians want to ensure that the cardiac program has the highest quality performance and patient care. The hospital and physicians, therefore, remain committed to achieving a high quality performance standard and continually improving the program in a systematic fashion.

Dr. Hoffman is a retired cardiothoracic surgeon. He serves as Medical Director of Perioperative Services and Medical Director of Cardiovascular Quality, Dayton Heart & Vascular Hospital at Good Samaritan.

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Agenda

- 6 p.m. Registration
- 6:15 p.m. Cocktails and
Hors d'oeuvres
Reception
- 7:15 p.m. Presentation
and Q and A

Weinberg Lecture FALL 2010 Schedule

Wednesday, September 15, 2010

The epidemic of CVD in the developing world: Global implications

Bernard J. Gersh, MB, ChB, DPhil, FRCP, FACC, PhD
Professor of Medicine, Mayo Clinic College of Medicine

*Consultant in Cardiovascular Diseases and Internal Medicine and
Associate Chair of Academic Affairs and Faculty Development in
the Division of Cardiovascular Diseases, Mayo Clinic Rochester,
Minnesota*

Wednesday, October 13, 2010

Mitral valve repair 1902-2010: Evolution and Revolution

Lawrence H. Cohn, MD
Hubbard Professor of Cardiac Surgery, Harvard Medical School

*Division of Cardiac Surgery, Brigham and Women's Hospital
Boston, Massachusetts*

Wednesday, November 10, 2010

Artificial Heart Valve: A 50 Year Journey

Lawrence I. Bonchek, MD
*Editor-in-Chief, Journal of Lancaster General Hospital
Lancaster, PA*