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SPECIAL ISSUE: CARDIOTHORACIC SURGERY

What's in a Name???

GOOD - authentic, honest, just, kind, pleasant, skillful, valid

NEIGHBOR - friend, near

ALLIANCE - affiliation, association, marriage, relationship

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COMMENTARIES

MY BLACK BAG

I use a traditional doctor's black leather bag. This is a rarity among physicians these days. In the hospital the doctors usually don't carry many tools. A stethoscope is required for almost all doctors. Other instruments are only uncommonly used, and are usually available at the nurses' station on every hospital unit. Neurologists use more tools than other doctors. A reflex hammer is a must, and a personal ophthalmoscope, although not *de rigueur*, is helpful, along with a couple of different tuning forks, and, occasionally some other devices, such as a card to test visual function, a special tape to evaluate eye movements, some smelly things to test olfaction, such as a small tube of toothpaste or a small vial with vanilla or almond scents, and perhaps some other arcana. Most younger neurologists carry canvas bags, less expensive, more practical and modern than the old style bag. I bought my bag in medical school, 30 years ago. It's seen its share of activity and shows it. It wasn't an expensive bag to begin with, and it apparently now looks like it's more of an heirloom than a piece of junk.

My patients often comment on my bag. These comments fall into two categories. One set of remarks is somewhat adulatory. "Was that doctor's bag your father's? It looks so well used. It must be very old. What a wonderful thing. I don't see many of these anymore." The other set of comments has a different perspective. "They're not paying you enough, eh, Doc? Maybe we can take up a collection to get you a new bag."

Recently a new patient told me that she was referred by a friend, who was a patient of mine. "She said I'd know you by your black bag. She said it looked well used."

Interestingly, perhaps, this bag actually has little, if any, sentimental attachment for me. I use it because it's there. It would cost me both time and money to replace, and it's not worth

either to me at this point. I've thought about using an attaché type of case that would allow me to carry both instruments and papers, the occasional outpatient chart I might need to see an in patient, but then I worry that I'll be more apt to lose it. I'm accustomed to putting the bag down in certain places as I evaluate a patient. I'm used to putting it between my arm and my side in some situations, or carrying it in my hand but by the straps in others. It's become part of me, in a way, although not, I think, in a sentimental way.

I think that my patients are disappointed when I tell them that the bag is not an heirloom, that I bought it in medical school. They seem to like that emotional attachment to medical things. The iconography of Dr Marcus Welby is alive and well, at least among the older patients, who grew up believing that the FBI and their family doctor were brilliant, caring, responsible and infallible. Both have fallen from grace over time (hopefully the latter less than the former) but the image persists. The doctor bag, one that looks like its seen its bit of activity, along with the gray hair, the unharried, unflappable and measured demeanor is part of that picture.

A relative, now in her second year of medical school, in the process of purchasing her clinical instruments, asked her mother, no longer working as a doctor, for hers. The daughter goes to the same medical school as her mom. The mother sent everything but the doctor bag. She didn't know if the daughter wanted it. After all, they're not widely used anymore. She didn't want to part with it unless it was going to be used. She liked the bag. It meant something to her. She wanted the bag to be wanted. When the daughter did ask for it, the mother was delighted and shined it up with shoe polish and sent it off. On the insurance form at the post office she checked the box, "irreplaceable." If it had been my bag I would simply have listed the cost of

a replacement, and not thought twice about it.

I wonder if my memories are less fond than hers, and if so, if that's because I'm still practicing and she's not, or if I'm just not sentimental. My bag's pretty banged up. Hers looks brand new after its buffing. Will the daughter care? I think so. And somehow, I don't know why, I think that the girl, not sentimental by nature, will care because her mother cared. And that's a good thing.

I think about my black bag and what it means. I won't replace it until it breaks. And when it does break I won't fix it. I'm pretty sure I'll throw it out and not give it to a relative or student. I'm hoping that the bag outlives my career so I won't have to worry about choosing between an expensive leather bag and a cheap, efficient canvas one.

Maybe I do care about the bag, and I wonder if I'd be a better doctor if I cared more. I wonder what it means when my patients care more about the bag than I do.

JOSEPH H. FRIEDMAN, MD

THERE'S NOTHING LIKE A REDHEAD!

British newspapers, earlier this year, carried an advertisement urging readers to switch to another brand of gasoline. The crucial phrase was the adage: "There are some things in life you can't choose." To illustrate this, they included a picture of a family, all with red hair. This generated many letters of protest from ginger-topped readers who were outraged that the natural color of their hair should be so disparaged, so demeaned. One indignant letter even labeled it as "reddism," akin to sexism.

Admittedly, the number of people born with red hair, a recessive hereditary trait, is small, with some estimates signifying that it is about 3% of humanity. And while red hair is encountered in every region and ethnic group, certain regions, such as Celtic northwestern Europe, are the sites of relatively large numbers. Tacitus, the Roman historian, described the Picts of northern Britain as having red hair and large limbs. In general, red-headedness seems to increase in frequency in the northern latitudes and diminish substantially in the tropics. The Scots, with the world's heaviest concentration of redheads, have ascribed many traits to these individuals, including a greater readiness to sunburn, a more fiery temperament, a more mercurial nature and a feisty personality. According to surveys of Scottish males, a red-headed league unto themselves, women with red hair are "more sexually attractive and vivacious".

The number of red-headed actresses in motion pictures far exceeds the 3% that one would anticipate if the trait were evenly distributed, thus giving some credence to the Scottish survey findings. A cursory review indicates that the following well-known performers are alleged to have been red-headed at birth: Lucille Ball, Clara Bow, Bette Davis, Greer Garson, Susan Hayward, Rita Hayworth, Katherine Hepburn, Deborah Kerr, Nicole Kidman, Shirley MacLain, Bette Midler, Maureen O'Hara, Julia Roberts and Ginger Rogers. [And, parenthetically, Queen Elizabeth I, Ann Boleyn, Nell Gwynn and Lilith.] Amongst male actors, there are Woody Allen, James Cagney, Van Johnson, Danny Kaye, Darren McGavin, Chuck Norris, Robert Redford, Red Skelton and Spencer Tracy.

Red hair is not unknown amongst great political leaders, such as Napoleon Bonaparte as well as a handful of American presidents from Thomas Jefferson to Dwight D. Eisenhower. Thor, the belligerent Nordic god of thunder and mayhem, is said to have been red-headed; but so, too, were the Cabbage Patch Kids and Raggedy Andy.

On the other hand, there are exceptional instances where red-headedness is brought on by severe malnutrition rather than by genetic predisposition. In 1934 Dr. Cicely Williams reported a severe form of protein-calorie nutritional deficiency in African infants, often emerging shortly after the infant ceases breast-feeding and is transferred to a calorie-poor, carbohydrate-rich diet. The hollow-eyed, affected infant shows failure of growth, pronounced swelling of the abdomen, lethargy, peeling skin and a lightening of its hair color, often assuming a distinct reddishness. Africans called such malnourished children

kwashiokor, meaning the displaced child. Kwashiokor children are often singled out by Western photographers when they wish to illustrate the gravity of famine in Africa. Kwashiokor has been only rarely encountered in Western regions although cases were noted in the starving children of the Warsaw ghetto during World War II.

Has science identified any biological attributes associated with conventional red-headedness? Certainly red-heads, almost always excessively fair-skinned, are more sensitive to ultraviolet radiation. But more important, they are also victims of a substantially higher frequency of skin cancer. This has puzzled scientists until recently when investigators, culturing the pigment-forming cells at the base of hair follicles, discovered that a crucial gene responsible for hair color is the melanocortin-1 receptor; and a single mutation of this gene seems to be the basis for the reddish hue of hair. And further, that the pigment-producing skin cells of red-heads and thus the cells containing this mutation, are quantitatively more vulnerable to a greater range of solar radiation. The ensuing cellular damage often leads to profound chemical changes in the skin culminating in disruption of the skin cell DNA which, in turn, often leads to a cancerous transformation.

Are there still other physiological ramifications of red-headedness? Another team of scientists has discovered that red-headed women [but not men] are more sensitive to the effects of certain pain-suppressing pharmaceutical agents and therefore require reduced dosages of the analgesic drug to achieve a satisfactory level of pain relief. On the other hand, red-heads, in general, need more general anesthesia than the average patient in order to reach a satisfactory level of relief from the pain associated with surgery.

These physiological observations in red-headed women suggest that the biochemical substrate which results in a distinctive hair color, may also affect the function of other organs, including the central nervous system. It is not a total stretch of the imagination to speculate that if the nervous system of red-headed women reacts differently to pain as well as to certain neurotropic medications, then such a modified nervous system might also alter the threshold levels for particular emotional states, and perhaps enhance still other, as yet unidentified, cognitive capabilities leading to intensified skills in acting.

A remark such as: "There's nothing like a redhead to liven things up," may seem, at first hearing, to be a prejudicial, intemperate and thoughtless outburst based on some unfounded Celtic myths. Yet, as the subtleties of the human genome gradually emerge, we may soon be confronted with the reality that red hair is but the projecting part of an extensive genetic iceberg; that a carrot-top is but one visible component of a bewilderingly complicated genetic constitution leading to certain aptitudes, certain attitudes and certain vulnerabilities that people may interpret variously as bawdy, louder than life or merely vivacious.

STANLEY M. ARONSON, MD

THE NEW AGE OF CARDIAC SURGERY DRIVEN BY TISSUE ENGINEERING AND BIOTECHNOLOGY

RICHARD A. HOPKINS, MD

In western societies heart disease has been the number one cause of death in the 20th century for men and women and remains the leading cause of death in the early 21st century. The surgical treatment of cardiac disease was essentially invented as an independent discipline in 1953 with the development of the **cardiopulmonary bypass (CPB)** or heart/lung machine by Gibbon and colleagues.¹ In 1954 only three hospitals in the country performed open-heart surgery using CPB; today there are over 2,000 cardiac surgery programs in the United States. As a field, cardiac surgery has evolved through three major periods. We are on the cusp of the fourth.

Era I, beginning in 1953, is “the anatomic period,” when surgeons sought to restore anatomy that looked like the normal heart, presuming that functional improvement would follow. So narrowing of vessels such as coarctation of the aorta were enlarged to normal diameters, openings which shouldn’t have stayed open such as patent ductus arteriosus were ligated, septal defects which did not establish the normal four independent chamber anatomy of the heart were closed with patches, stenotic valves were opened to be less stenotic and leaking valves were repaired and then after 1961 (clinical availability of the Starr-Edwards ball and cage valve), replaced to maintain forward blood flow. During this time, the emphasis was on the development of sophisticated and efficient surgical techniques, using basic tools adapted from other surgical disciplines and inventing new ones, the generalized improvements in cardiopulmonary bypass mechanical support and refinement of anesthesiologic techniques to match the challenges of the open heart surgical patient.

In the 1970s, laboratory and clinical research efforts focused on metabolic and functional performance of heart muscle regionally and the heart as a global pumping entity. Thus began **Era II**, emphasizing cardiac physiology/pharmacology refinements. Inotropic support became multi-model pharmacology with after-load reduction and mechanical intra-aortic balloon support. In this fruitful era, stark mortality rates as high as 25-50% for many standard diagnoses fell to low single digits. Methods for cooling and stilling the heart such as cardioplegia and deep hypothermia-total circulatory arrest allowed even more complex, minute, and technically demanding surgical procedures to be routinely performed.

Subsequently, the current **Era III** features electromechanical engineering, marked by the application of sophisticated electrical, electronic and mechanical engineering solutions, often referred to as “space age” technology. The mechanical and electronic support systems have multiplied, becoming more sophisticated and miniaturized. They often replicate physiologic feedback signaling systems. Pacemakers have shrunk from 6 oz.-

5 inch diameter 1-inch thick monstrosities to wafer-thin implants the size of a quarter or half dollar. More valve replacement options have become available, and complex reconstructive surgeries were developed. Advances in pharmacology, ventricular support pumps, cardiac transplantation, and even variably successful artificial hearts have sustained life beyond the functional cardiac expectancy for many patients.

These articles represent examples of the achievements of these three phases, which presage **Era IV**. High-resolution cardiac magnetic resonance imaging allows a precision of diagnosis combined with functional assessments to calibrate physiologic status and anatomical detail to a level that could only be imagined and hoped for a few years ago (Dr. Atalay). It is possible to enter the operating room with very few questions or uncertainties about the anatomical or physiologic status of the patient’s heart. Even those can be visualized, tracked and the accuracy of the surgical repairs defined by intraoperative TEE (Dr. Bert). While always a close team, today the cardiac surgeon-cardiac anesthesiologist are truly joined at the hip. Recognizing the stress and trauma of the surgical experience itself, a major theme of the past few years has been to develop surgical methods for performing highly accurate and sophisticated surgical procedures without of placing the patient on cardiopulmonary bypass machines. So called “beating heart” or “off bypass” surgery reduces the overall stress and inflammatory biochemical trauma of standard open-heart surgery with theoretical and realized benefits for all potential candidates for this type of surgery (Dr. Lilly). A parallel set of developments, under the same principle of reducing the stress of cardiac surgery, spurred development of minimal incisions, “key-hole” surgery, partial sternotomy for aortic valve replacements, valve repairs instead of replacements, robotic and port access or video-assisted cardiac surgical procedures. Endoscopic procedures for harvesting veins, radial arteries, and internal mammary arteries are also used in Providence to reduce the trauma of conduit acquisition for coronary bypass surgery. Finally, the development of reconstructive cardiac surgery as an evolving field within the discipline of cardiac surgery has resulted in tremendous advances in the management of valvular and congenital heart disease. Amazing procedures are now routine for the reconstructive heart surgeon (as is the field of choice of this author) including multi-valve repairs, multiple options for valve replacements to optimize the prosthesis to the specific patient (e.g. homograft valves, stentless tissue aortic root valves, mitral valves treated with anticalcification agents, valve salvage, etc.) and the use of valve transplants, autologous valve switches and physiologic repairs that are very different in approach from simple mechanical valve replacement options.² Additionally, the cardiac surgeon can improve the electrical status of the heart

(discussed by Dr. Cooper with the MAZE operations); the consequences of pressure and volume overload causing geometric alterations and dilatation of the heart chambers can now be attacked directly by architectural revisions of the heart chambers termed ventricular remodeling, reduction atrialplasty, and other unique procedures. The survival of children following surgery for congenital heart disease has spurred the development of yet another subspecialty: adult reoperative congenital cardiac surgery. And finally, for atherosclerotic of cardiovascular diseases, the improvement in lipid control and catheter based technologies for the dilatation and stenting of coronary lesions has led to an overall reduction in candidates for coronary bypass surgery, leaving the surgical option primarily for patients with extremely extensive disease, complicating factors which disallow catheter approaches or secondary related cardiac problems requiring structural repair in addition to coronary surgery. With the later onset of disease, the patients managed surgically are older, have greater comorbidities, express a higher incidence of previous strokes, hypertension, and diabetes. Remarkably, surgical outcomes have improved or remained stable, even as the substrate of patients becomes more challenging.

We are on the cusp of perhaps the most exciting era: **Era IV- the new age of tissue, cell and gene engineering**, when we will be surgically managing the heart using autologous tissue reconstructions or replacing parts with bioengineered functional hybrid components that are alive with tissue and cells compatible with the recipient patient or even adding cells containing genes designed to drive the production of salubrious proteins or other moieties to improve myocardial function, reduce ventricular loads, reduce inflammation or slow rejection of a heart transplant.

TISSUE ENGINEERED HEART VALVE: A PARADIGM FOR ERA IV

Cardiac surgery will be evolving from an emphasis on technical expertise, and understanding of the anatomy and physiology of the pathologic heart to an era when the cardiac surgeon must also must understand molecular biology, tissue engineering, cell-cell signaling and the subtleties of inflammatory pathways. While always a demanding subspecialty, cardiac surgery will return to its scientific roots requiring the most expert of technical surgeons who have good decision-making qualities **and** top grade scientific and mathematical competencies. These articles seek to provide a glimpse of the depth and breadth of what is available in Rhode Island but even more importantly, to develop an appreciation by the reader for the launching pad on which we find ourselves: **Cardiac Surgery – Era IV!**

Our cardiac surgical research laboratories at Rhode Island Hospital and Brown University are in the forefront of the tissue-engineered heart valve effort. All manufactured heart valves are imperfect. Whether derived from a pig, cow, horse or made of pyrolytic carbon and mechanical components, all prosthetic heart valves are liable to certain

problems. First, they are not (from a hydraulic engineering standpoint) as efficient or effective as the native valve engineered by the best Engineer ever; all have gradients and are liable to patient-prosthesis mismatch. All are prone to a greater or lesser degree to thrombosis, emboli and blood component destruction. All are liable to prosthetic valve endocarditis and all have durability issues that range from two years in some children to 15-20 years in the older adults. Many are noisy and some are difficult to implant. The ideal heart valve replacement would be living, non-thrombotic, resist infection as normal tissue, able to adapt to changing circumstances (for example the development of hypertension), grow and repair itself. For the past ten years in the Collis Cardiac Surgical Research Laboratory of Brown University at Rhode Island Hospital, we have been studying various types of tissue engineered heart valves to the point that over 200 hundred sheep have been implanted with such valves. The best performing valves are derived by decellularizing allograft heart valves, thereby removing all antigenic material while retaining the design advantages of native valves. While lifesaving, and the best available option for many patients, clinically utilized homograft valves (obtained from cadavers, cryopreserved and banked) contain donor cells and can be both proinflammatory and antigenic. The decellularized heart valve scaffolds are not stimulating as all HLA and ABO antigens have been removed.³⁻⁵ Tissue engineering implies the use of a scaffold design, which in this case is the design of the normal semilunar heart valve and the application of cells, which are appropriate to the functional implant site. We have derived these cells from heart valves by biopsy and expanding the cell population with *in vitro* amplification techniques for seeding the valve.^{6,7} In addition, our seeding technology has taught us methods to attract (by in-migration) appropriate cell phenotypes form the host local milieu to autologously recellularize the decellularized scaffolds. (Figures 1-7) We are close to multi-center clinical trials perhaps within the next 1-2 years with a non-valved patch or conduit (LifeNet, Norfolk, VA) and probably within the next 5 years to having actual functioning, human, tissue engineered, viable, *personal*, pulmonary and aortic valves.^{8,9} Extension of the tissue engineered aortic valve technology to the pulmonary valve will be relatively easy but additional technical hurdles exist in the development of AV valves (mitral and tricuspid) as a consequence of the dynamic contribution of the subvalvular apparatus (muscles, chords, etc.) in the function of these valves. There are many additional bioengineering and biotechnology projects related to the cardiac subsystem being evaluated including scaffolds recellularized with functioning heart muscle cells and then sewn into the heart wall to replace scarred and dead heart tissue. Other cell-based gene therapy methods include projects in our laboratory to deliver appropriate protein moieties to mitigate or reverse disease processes directly within the heart. Obviously such procedures will not be analogous to current cardiac surgeries and in fact within 10 years will likely be the majority of the work of

cardiac surgeons. Traditional outcomes analysis will be difficult based upon the uniqueness of each operation.¹⁰⁻¹³

Prosthetic valve replacement options have advantages and disadvantages, which are design and product specific. We discuss these with patients on a daily basis in an attempt to fit the best currently available clinical option to their lifestyle, age, co-morbidities, patho-physiology and anatomy. A truly tissue engineered heart valve will consist of a human semilunar valve scaffold that has been decellularized and rendered non-antigenic and then repopulated in the matrix by host cells which can then provide the functions of a living tissue: i.e. growing, healing, cell and matrix regeneration, resistance to infection (immune function), and the modification of extracellular matrix and biologically active compounds in response to changing hemodynamics and patient age. Theoretically, the patient should never need a reoperation. Such tissue engineered solutions will require reconstructive surgical techniques perhaps more analogous to congenital heart surgery than currently practiced adult cardiac surgery.¹⁴ The tissue engineered heart valve project in the Collis Cardiac Surgical Research Laboratory of the Rhode Island Hospital and Brown University utilizes decellularized aortic mammalian semilunar valves. Since the matrix proteins are antigenic across mammalian species, such experiments must be performed in an animal model utilizing animal proteins and tissues. The juvenile sheep model is extremely rigorous and demanding, as any tendency for inflammation or degeneration results in accelerated calcification in this animal. Thus, it is the preferred FDA recommended model for testing of biological heart valves prior to proceeding to human studies (ISO 5840:1996 and FDA Replacement Heart Valve Guidance Document: 1994). And as the figures demonstrate, recellularization does occur and the valves perform functionally (by echocardiography, cardiac catheterization and autopsy evaluation) as a semilunar valve should without stenosis or regurgitation. Experiments designed to more fully understand this recellularization process are currently being performed in our laboratory. Such material could be used to repair aortic and pulmonary artery defects and rather than becoming calcified, as non-living patches, these patches will instead actually recellularize and become living, integrated, structural tissue components of the great vessel wall. This will potentially allow for the Holy Grail of replacement cardiac components—**growth**. The ability to remodel, grow, enlarge and adapt is the *sine qua non* of normal living tissues.

Era IV will challenge our practice of cardiac care, including training requirements, outcome analysis, definitions of quality and value, definitions of a clinical “Center of Excellence,” leadership, and even the economics of surgery, cardiology care, and in-patient services. On the dawn of this **Era IV**, hurdles appear surmountable with the application of good science, leadership by clinician-scientists, and provision of the critical resources of time and money, and real commitment to support academic (i.e. research driven, evidence-based) clinical leadership by the

administrators of hospital-centric clinical enterprises and their education-centric University/medical school partners. To not participate in **Era IV** is for a Medical Center to be relegated to 1^o and urgent care outpost roles (i.e. big, fancy, expensive, and likely inefficient “Doc in the Boxes”) and to forever be left in the dust of bygone eras, while referring their patients to other medical centers that had the foresight and vision to have participated in development of cutting edge therapies.

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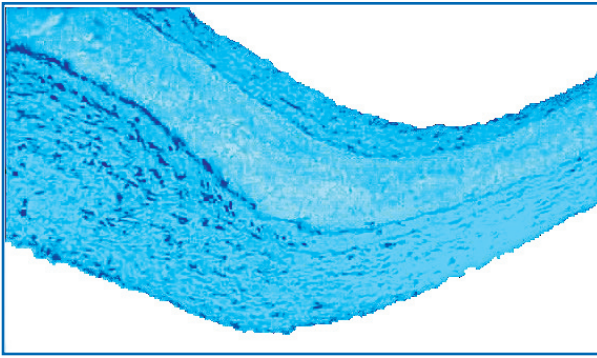


Figure 1: This demonstrates an explanted semilunar valve leaflet, which was implanted as a living cryopreserved (not tissue engineered) heart valve similar to what is currently clinically used today. Cryopreserved heart valve bank is available at Hasbro/Rhode Island Hospital and many other hospitals around the country. We use and value such valves as extremely valuable options for patients who are not suitable for typical manufactured prostheses (xenograft or mechanical). The surgery represents a human valve transplant utilizing tissue resourced from a cadaver donor (usually gifted during a multi-organ/tissue donor retrieval). The appropriate sized valve is thawed in the operating room and sewn into the appropriate position in the heart. This is an important histologic picture as it demonstrates that the transplanted valve leaflet becomes acellular over time and in fact remains functional due to a fibrous sheath that the recipient patients own body lays down over the functioning valve leaflet. This splints the “dead” leaflet and is the functioning entity of the heart valve. Such valves have functioned for over 25 years in many adult patients including the first patient who received such a “homograft” valve in 1962 and subsequently bore three children and was alive in 1985 when Dr. Hopkins met her in England.



Figure 2: Heart valve leaflet after decellularization. An acellular scaffold with mechanical integrity sufficient to perform functionally as a non-living heart valve, with the available voids and spaces for recellularization.

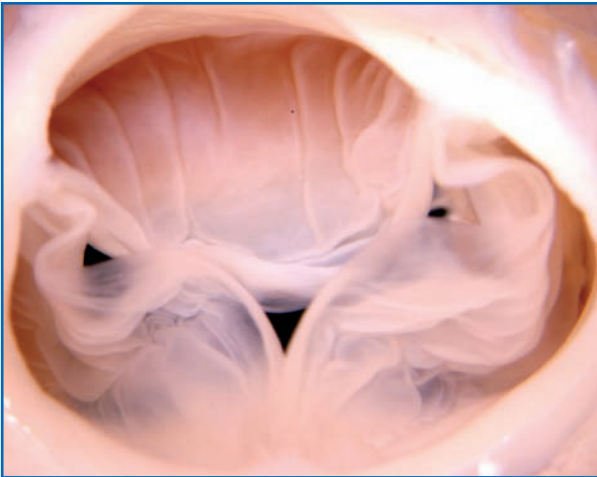


Figure 3: Macro-photograph of an ovine pulmonary valve following decellularization procedure demonstrating that the valve appears essentially normal.

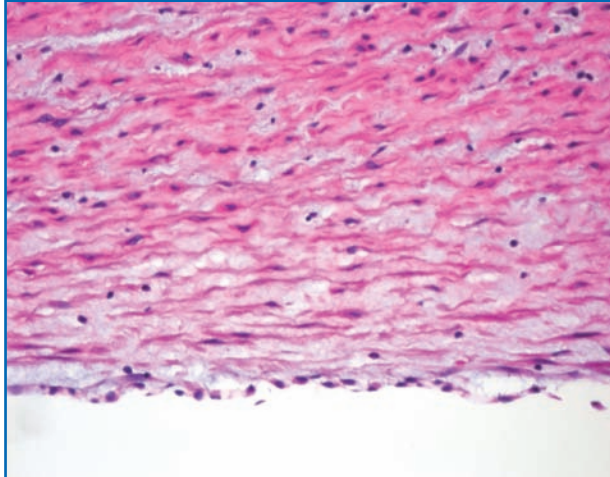


Figure 4: Histology of pulmonary artery sinus wall from a pulmonary ovine valve explanted at 20-weeks following pulmonary valve replacement demonstrating recellularization through the matrix by myofibroblasts, and early luminal endothelialization.

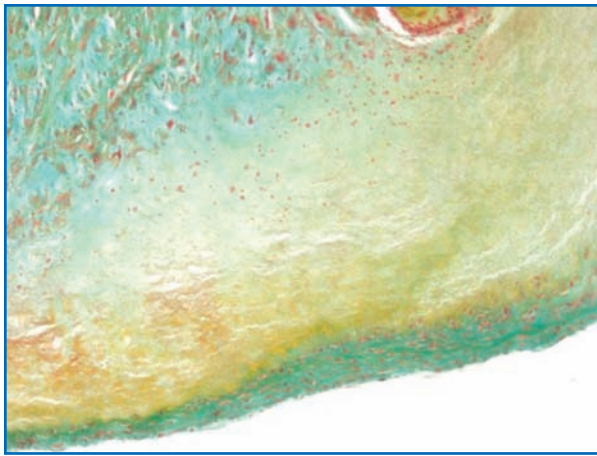


Figure 5: Movat's pentachrome photomicrograph showing migration of cells advancing as a wavefront from the adventitial side (top) towards the lumen (bottom) where additional recellularization has occurred. Over time these cells progress entirely through the acellular wall matrix and recellularize the tissue completely. Additional immunohistochemical studies have shown that the advancing wavefronts are of sequentially different cell types. Ultimately, the predominate cell becomes the appropriate phenotype of interstitial heart valve tissue, **the myofibroblast** as defined by immunoblotting and immunohistochemistry for alpha smooth muscle actin, colligin (HSP-47 collagen synthesis intracellular chaperone) among many other phenotype characteristics assayed in Dr. Hopkins' laboratory.¹⁵ Ground substance is being secreted by the cells just behind the wavefront as demonstrated in the Movat's stain as the blue-stained areas at the top. Such ground substance includes fibronectin, chondroitin sulfate, and other soluble proteins and lipopolysaccharides. The advancing wavefront is spearheaded by macrophages (not lymphocytes).¹⁶



Figure 6: Collis Laboratory research team operating to insert a tissue engineered heart valve. Pictured is one of the Roddy Scholars in Cardiac Surgery Research, Dr. Roh Yanagida.

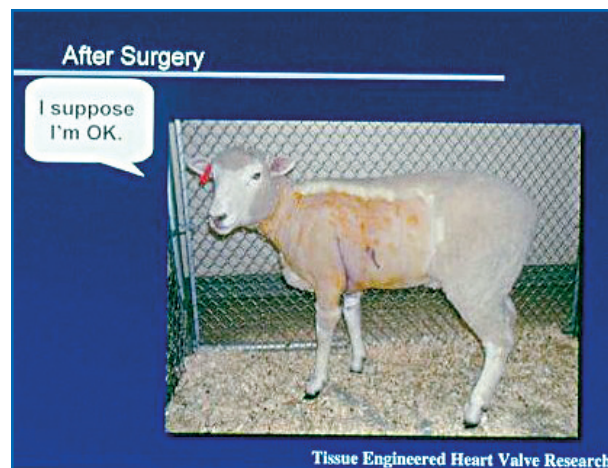


Figure 7: This demonstrates a tissue engineered heart valve recipient the evening after surgery. The sheep are typically up, eating and comfortable. As noted the incision is extremely small and are very well tolerated by the sheep. All of the sheep utilized are female to avoid social strife but somehow (!) at least one sheep, whose heart functioned normally with the tissue engineered heart valve, successfully carried and birthed a lamb after implantation.

CARDIAC OUTCOMES ASSESSMENT AND QUALITY MANAGEMENT

RICHARD A. HOPKINS, MD

Cardiac surgery patient operative outcomes have been the most tracked, scored, analyzed, and assessed procedures in the history of medicine. Cardiac surgeons are the most subjectively and objectively "scored" subspecialists in clinical medicine. In 1989, the **Society of Thoracic Surgeons (STS)** began a voluntary database that to this day is the most effective, accurate and statistically rigorous effort to record, analyze, and relate outcomes to quality improvement.^{1,2} More than 2 million surgical procedures from over 70% of the hospitals performing heart surgery are archived in the STS database. Approximately 200,000 patients (with 2000 data points/patient) are entered each year nationally.

The most frequent operation within that database is the **coronary artery bypass procedure (CABG)**, which has allowed a tracking of expected outcomes in patients with specific risk profiles that is matched in accuracy and quality by no other database or analytic procedure; 23 critical pre-operative variables are used to create algorithms to estimate a patient's risk of death or morbidity categorically for a specific cardiac surgical operation based upon the expected outcomes of all similar patients previously enrolled in the database, weighting the most recent enrollees higher than older historical data input. This provides MDs and patients a realistic assessment of risk. Stratification into up to 10 different risk categories on a continuous scale allows more valid comparison of outcomes amongst programs as compared to national statistical outcomes. It also has allowed tracking national trends in patient characteristics over time. For example, over the past 4 years patients undergoing CABG are older, heavier, have a greater incidence of diabetes and pre-existing diagnoses of cerebral vascular and peripheral vascular disease versus patients prior to the year 2000. As a consequence, the increased preoperative severity of medical illnesses and co-morbidities is responsible for elevations in intra-

operative and postoperative morbidities (e.g. increased requirement for blood transfusion, longer postoperative ventilator times and more hospital readmissions within 30 days after discharge). Despite the increased morbidity, the mortality rates have remained stable or declined. The overall operative mortality from 1995-1999 for CABG was 3.3% declining to 2.6% in the time period 2000-2004.³ Low-risk patients (with a predicted mortality of less than 2%) sustained a mortality rate of 0.79% and patients categorized as high mortality risk (i.e. greater than 2% risk of death) sustained perioperative mortalities at 5.37%. Because of the extreme low frequency of death in the low-risk patients, it is, for all practical purposes, impossible for individual cardiologists to assess significant differences among surgical providers for low risk patients. High-risk patients are so variable that without strict application of criteria, valid observed-to-expected death rates cannot be discerned casually and again because of low frequency of the various diagnostic categories denominators can vary widely from year-to-year. O/E ratio = to 1.0 means that for the specific risk profile the expected mortality is being realized. We became STS database participants on the author's arrival in Providence in 1996. The Lifespan Hospitals and their surgeons have consistently had O/E's at or below 1.0 (and way below 1.0 ratios in some time periods) for virtually all major categories of surgeries.

Databases are at their best when assessing programs with large volume subsets. Other methods, especially those using administrative data, are prone to egregious errors, are notoriously subject to biased reporting and are totally inadequate for assessing quality.¹ These include all "analyses" based on the administrative data sets reported by hospitals for the Medicare subset as available under the Freedom of Information Act. A small cottage industry of internet-based "rating services" markets to the consumer the bo-

gus concept that the quality of a cardiac surgical program can be ranked in a 1-5 star order, like hotels. The data used for these proprietary-rating systems are fundamentally flawed and ill-suited for outcomes research (business administration data and hospital coding for Medicare reimbursement). Their algorithms are rarely published, and the results are highly subject to bias and modeling manipulations. Most importantly, morphing such data into "ratings" does not denote quality. Statisticians, epidemiologists, and cardiac disease specialists have consistently condemned these ratings as unsuitable for making quality comparisons.³⁻¹⁰

In studies on entry data quality, the STS found its database quality to be extraordinarily high with discrepancies less than 5% in audited fields when on-site "real time" quality control was performed by a Division of Cardiac Surgery. The relational database has allowed comparison of mortality and other post-operative outcomes such as hours on the ventilator, etc. to be used for quality improvement programs in hospitals as well as tracking key quality indicators such as sternal wound infections, leg wound infections, strokes, etc. Interestingly the post-operative length of stay while gradually decreasing around the country to a minimum of 6.3 days following CABG (similar to RI) seems to be rising as a consequence of the higher age and elevated co-morbidities in patients referred for a surgical revascularizations. STS data have also been used to compare outcomes of CABG in large datasets for comparison to percutaneous coronary interventions or medical management of coronary disease including, stable angina, or stress-induced ischemia. The Medicine, Angioplasty, or Surgery study (Mass-II) [*Journal of American College of Cardiology*] reported on the key summation outcome: the likelihood of survival free of cardiac mortality, unstable angina, need for revascularization or myocardial infarction among the three treatment groups.

The best event-free survival was with CABG at 94%; the second was medical therapy at 89%; the worst outcome was with percutaneous intervention at 76% ($P<0.0001$).⁴

Such statistical analyses and comparison of local outcomes with very large regional and national datasets have allowed a degree of precision in assessing outcomes that is unparalleled in the history of medicine. At least one operation (CABG) has a fairly consistent population subset, has distinct variations in techniques which can be identified and correlated to outcome and due to the large denominator allows (at least in some cases) comparison of the outcomes of one hospital or program to another. Comparisons of surgeons to each other or to normative values is difficult without large numbers of similar patients. But over time a general picture can emerge. What has been shown to be likely true is that low volume surgeons in low volume programs do not have outcomes quite as good as low volume surgeons in high volume programs who perform essentially as well as high volume surgeons in high volume programs.³ While perhaps not intuitively obvious why, the high volume issue actually becomes important mostly for high-risk esoteric cases (e.g. transplant, arterial switch, etc.). Data suggest that an adult cardiac surgical program (i.e. a hospital) should perform ≥ 600 cases/year. That would give individual surgeons the best opportunity to perform well and essentially guarantee patients better-than-average results at that hospital.

Interestingly, the **CHSS (Congenital Heart Surgeons Society)** and the STS databases for pediatric congenital heart disease, as well as analogous European databases, have demonstrated that surgeon and hospital case volumes are not a predictor of complex congenital surgeries patient survival¹¹ while lesion, surgical complexity and patient-based factors drive outcomes. One explanation has been proffered – that congenital heart surgeons are a select and perhaps elite subgroup of their training “class” and spend more years in training both as fellows and as a junior staff “apprentices.” Thus the more experience, more maturity,

and greater technical expertise combined with a specialty that includes a vast array of procedures, usually technically and time pressured which demands surgeons of competency results in outcomes data suggesting that for both adult and pediatric procedures, surgeon-based variability is neutralized to a great extent (i.e. either by filtering out lesser qualified trainees or by delivering higher quality training, virtually all of these surgeons, are good to excellent).

Assessment of an individual surgeon's results is tricky - analogous to assessing the hitting ability of a baseball player. In the major leagues it is difficult to assess individual bunting ability statistically because bunts are rare. But, for hitting, a starting player typically has 3-4 at bats per game; over the course of a season of 160 games he will have 300-500/ outcomes/year ($N=4000$ /for a 10-year career). These are the numbers needed for statistically valid comparisons. Probably no sport is more statistically driven than baseball and has fascinated statisticians (analogous to cardiac surgery). The batting average norm across professional baseball continues to be approximately 275 (i.e. out of 1000 at bat 275 times a hit will be accomplished). But is a 300 BA better than a 290? In many cases, no (e.g. if the 290 player always hits homeruns and the 300 hitter only singles). Many fans believe in streaks - runs of good hitting and bad hitting. When rigorous statistical methods are applied, the evidence for true streakiness is minimal and can be demonstrated only in a few players since data have been archived (essentially since 1904). 12 at bats with either zero hits or with 12 consecutive hits is a meaningless observation in valuing the offensive ability of a hitter; similarly 12 sequential operations (or even 100 of different types) cannot provide an adequate database on which to assess a single surgeon as “better” although it can identify outcomes that are truly horrible (i.e. 2 standard deviations off the norm). The analogy to baseball raises even trickier problems: the value of a given operation (or a given at bat) depends (under the best of circumstances) upon the level of risk for mortality, (i.e. strikeout, the degree

of difficulty to hit a specific pitcher) and the operation being attempted (i.e. is the batter trying to get a home run or just a hit?). The first problem is modeled in the STS algorithms by assessing the degree of risk that the individual patient exhibits based upon preoperative characteristics. The second issue has been harder to manage; “Olympic scoring”¹² does address this, for example a simple swan dive may have a degree of difficulty of three where as a 2 ½ somersault-gainer with a half twist may have a degree of difficulty of 7. Accomplishing a perfect 10 on each gives the diver a score of 30 for the first and a score of 70 for the second. But cardiac operations which may have a better outcome for the patient but which are technically more challenging to perform are not perceived differently. Thus, when limiting outcome assessment even to current STS type of measurements, there is a bias or pressure built in for the surgeon to perform the simplest operation, not necessarily the best operation, as he is scored on patient based risk factors over which he has no control and the diagnosis (e.g. CAD or aortic valve) but not the actual operation performed. To carry the baseball analogy further – this is like limiting hitting assessment to batting average only, while ignoring other measures such as slugging %, on base %, etc. Thus, a heart valve transplant which is more technically demanding than the implantation of mechanical prosthesis is perceived by the patient (and often the cardiology community) as the same operation (i.e. valve replacement) but the outcome for the patient with the mechanical valve may be less salubrious due to mandatory Coumadin therapy and anti-coagulation related life threatening complications which approach 100% over 10-15 years; whereas the more surgically challenging valve transplant procedure (which does not need anticoagulation) may give perfect hemodynamics and unload the heart to the point that left ventricular muscle mass returns to normal and the patient lives a normal life being able to undertake all physical activities including those that have risk of bleeding. Even STS scoring does not account for such higher

“value” options or Olympic scoring “difficulty” nor are batting averages weighted differently when the batter faces Nolan Ryan versus a new rookie just up from minors. The Congenital Heart Surgeon’s Society in the United States and sister organizations around the world have attempted to develop scoring systems for degree of difficulty for operations (e.g. RACHS-1, Aristotle). Such methods are in their infancy but will be a great step forward in the measurement of outcomes based not only on patient-based profiles of risk but also upon surgical intended quality and the inherent technical difficulty of various therapeutic procedures.^{13,14} Of course, this means quantitating “value”, which will become even more important in **Era IV** (*vida infra*).

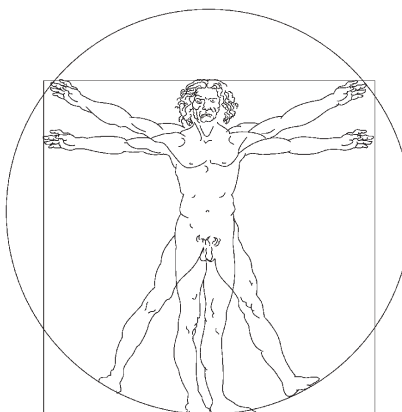
There is another other statistical anomaly, mathematically inherent to virtually all such assessments. Since at the low end of risk, mortality still has to be a positive number (there can be no negative mortality rates) then there are obligatory mathematical consequences of overestimating risk; similarly at the other end of the curve (high risk- high mortality), one cannot have more than 100% mortality, so the regression curve tends to underestimate risk. If one surgeon has a low risk patient mix, the numbers may overestimate quality of outcomes when compared to a surgeon whose case mix profile includes more high-risk patients. Thus an analyst must carefully analyze the data before reaching comparative conclusions.

This discussion highlights the difficulty inherent in quality management and outcome assessment. Fewer “routine” or “bread and butter” type procedures (e.g. simple, straight-forward 3-5 vessel coronary vessel bypass grafting) will be performed. In addition, the standard median sternotomy (on cardiopulmonary bypass) procedure, which has been refined since the 1960s to an extraordinarily low level of mortality and morbidity, may be minimized as enthusiasm builds for off-bypass, minimally invasive and less traumatic procedures. The challenge to the profession will be to evolve these technological and surgical approaches in such a way that the outcomes are not compromised. Ad-

ditionally, with the advent of stenting and percutaneous procedures and thus the lack of referral for second opinions on the relative value of surgical options, patients are being treated with “simpler” but perhaps less effective modalities.¹⁵ Simpler or less invasive are not the same as safer or more effective. Patients referred for surgery are now more complicated, sicker, are more variable in their presentations and have sustained many more previous procedures, thereby increasing their overall risk profile for the surgery. This trend will continue. New strategies will have to be developed to minimize the surgical risks, which likely will require increased amounts of technology, team surgery and advanced methods that will include biological adjuvants along with the anatomical interventions. For example, coronary bypass surgery may be combined with treatment of ventricular scars by replacing the dead tissue with living functioning myocardial implants and the reduction of electrical arrhythmias by MAZE-like management of the electrical substrates. Gene therapy will likely be cell-based and delivered during surgery to specific areas in the heart necessary to reduce the progression of arteriosclerosis, to improve heart muscle function, or valve function. To reduce the downstream consequences of long standing heart disease such as pulmonary valvular regurgitation complicated by pulmonary hypertension, pulmonary valves (tissue engineered or native) may be seeded with genetically modified cells that secrete pulmonary vasodilating proteins directly into the pulmonary circulation. To a great extent, each of these operations will be a hybrid of surgical virtuosity, technical sophistication, and advanced biomedical and cell/tissue engineering methods. Achieving the expertise to manage these aspects of cardiac surgery of the future will require very different training than has been the case for cardiac surgeons over the past 40 years.¹⁶ Sorting out competing strategies for the benefit of specific patients will require dispassionate and statistically rigorous assessments.

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EVALUATION OF THE CARDIAC SURGERY PATIENT BY MRI AND CT IMAGING: THE STATE OF THE ART

MICHAEL K. ATALAY, MD, PHD

Over the past few years, the landscape of non-invasive cardiovascular imaging has changed dramatically. Several recent technological advances have made magnetic resonance imaging and computed tomography clinically relevant modalities.¹⁻³ Both are rapidly gaining acceptance in the medical community and both offer the promise of continued growth and development. Each modality has unique strengths and weaknesses; in many ways the two technologies complement one another.

This article briefly discusses the technology behind these imaging modalities, the developments leading to their rapid entrée into the clinical arena, their clinical indications, and their roles in the evaluation of patients anticipating cardiac surgery. While MRI and CT are relative newcomers in the world of cardiac imaging, MRI is presently slightly more advanced in its cardiac applications and utility and will receive the bulk of attention in this article. However, CT is an inherently useful tool that is poised to establish itself as a credible non-invasive alternative to diagnostic cardiac catheterization in the assessment of obstructive coronary artery disease. (Table 1)

Although the application of advanced cross-sectional imaging for

peripheral vascular disease is not discussed in this article, significant gains have been witnessed on this front as well. Not-surprisingly, as their confidence with peripheral MR and CT angiography grows, cardiovascular physicians are increasingly planning procedures on the basis of non-invasive data alone.

CLINICAL CARDIOVASCULAR MRI (CMR)

MRI of the heart has been performed on a limited clinical basis since the early 1980s. Until recently, routine clinical application was hindered by the inability to freeze cardiac motion, long scan times, and low contrast between blood pool and myocardium. Owing to significant developments in software design, MRI has emerged as a versatile and reliable method for imaging cardiac anatomy and function.^{1,4-6} With data acquisition triggered by the ECG signal (so-called ECG-gating) stop-action, highly detailed images of the heart are possible. When multiple images at different cardiac phases are displayed serially, movies of myocardial contraction can be generated. In this way, even very rapid and subtle motions can be accurately depicted.

MRI is a safe technology that employs benign radiofrequency waves to interrogate soft tissues. It has high

spatial resolution (~50x nuclear cardiology), high temporal resolution (~40 ms), and excellent tissue contrast. Unlike echocardiography and nuclear cardiology, MRI is not significantly hampered by patient habitus. Although field of view, signal-to-noise ratio, and resolution may be affected on MR imaging, issues such as soft tissue attenuation and poor acoustic windows do not arise. CMR has the usual relative and absolute contraindications of general MRI and may be limited by severe cardiac arrhythmia or the inability of subjects to perform breath holds. In general, these limitations can be addressed and diagnostic studies obtained. There are several widely accepted indications for CMR. (Table 2) Most of these indications are relevant to the cardiovascular surgeon and are discussed below.

MRI also benefits from safe contrast agents that are non-nephrotoxic and non-allergenic. Their use in **MR angiography (MRA)** is well appreciated. Among the many recent developments in CMR, one that stands out is the demonstration that MR contrast agents can be used to accurately delineate areas of myocardial infarction.^{7,8} In fact, in addition to being regarded as the gold standard for the assessment of global and regional myocardial contractile function, many feel that MRI

Table 1. Advantages and Disadvantages of MRI and CT modalities.

	<i>Advantages</i>	<i>Disadvantages</i>
MRI	<ul style="list-style-type: none"> • Safe (no ionizing radiation) • Contrast agents are safe • <i>3D technique</i>—reconstruct images in any orientation • High spatial resolution • Very high temporal resolution • Excellent soft tissue contrast 	<ul style="list-style-type: none"> • Long scan times (30-75 min) • Cannot image calcification/bone • Standard MRI contraindications (e.g. pacemaker) • Claustrophobia • Not as readily accessible • Foreign matter causes artifacts
CT	<ul style="list-style-type: none"> • Very fast (seconds) • Very high spatial resolution; Moderate temporal resolution • <i>3D technique</i> • Can visualize & identify (a) calcium, (b) air in abnormal locations, (c) radiodense foreign matter • Convenient 	<ul style="list-style-type: none"> • Ionizing radiation • Contrast agents have finite risk of allergy and renal toxicity • Requires breath-hold • For cardiac imaging, regular, low heart rate is necessary

also serves as a new reference standard for myocardial viability. In the setting of ischemic heart disease the likelihood of a dysfunctional myocardial segment to improve function following revascularization is inversely related to the transmural extent of infarction as defined on CMR imaging.⁸ **Figure 1** shows a representative viability image alongside a single frame from a movie loop acquired at the same slice position. Small subendocardial infarcts—appearing as bright regions of muscle adjacent to the ventricular cavity—are seen in the inferolateral and anteroseptal segments at this short-axis level.

In addition to evaluating contractile function and cardiac morphology, MRI can be used to study blood flow physiology. Phase contrast imaging is an MR technique for quantifying blood flow.⁹ Applications include the quantitative assessment of instantaneous and time averaged blood flow in major arteries and estimation of peak systolic velocities across stenotic lesions, including valves. Flow data can be used to calculate shunt fractions and to estimate regurgitant volumes through valve lesions. Phase contrast imaging can also provide qualitative information; this is demonstrated in **Figure 2** where left-to-right blood flow across an atrial septal defect is portrayed by a black jet originating from the inter-atrial septum. This was a new diagnosis of ASD.

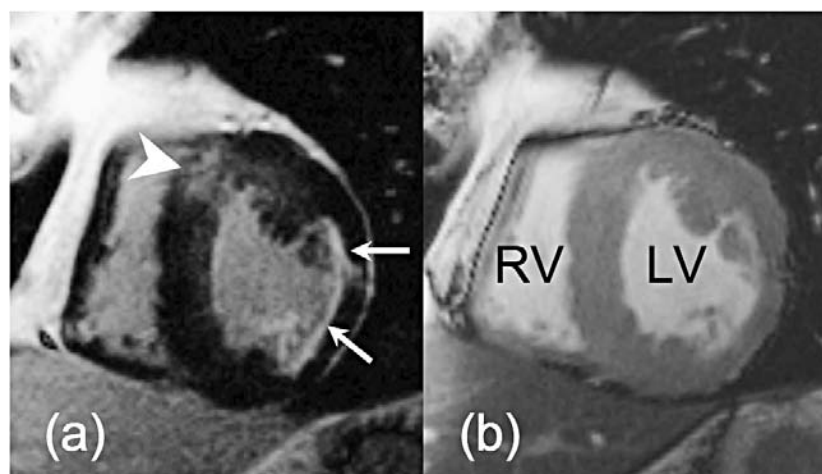


Figure 1. MR images from a patient with a history of myocardial infarction. Image (a) is a short axis viability image in which normal myocardium is black and infarct is bright. On short axis imaging the left ventricle (LV) is a circle and the right ventricle (RV) a crescent. Subendocardial scar is seen in the inferolateral (arrows) and anteroseptal (arrowhead) segments. Image (b) depicts a single cardiac phase in the movie series at the same slice position as (a).

CLINICAL CARDIOVASCULAR CT (CCT)

Conventional, non-ECG-gated CT is a readily available, widely used technique for imaging the anatomy of the cardiovascular system. CT is generally accurate in evaluating gross cardiac chamber size and configuration, pericardium, intra- and extra-cardiac masses, vascular anatomy, and various diseases of the aorta and great vessels. The chief benefits of this modality to the cardiothoracic surgeon have traditionally been (a) understanding the 3-dimensional anatomy before and after intervention, (b) identifying extent of disease and co-morbid conditions, and (c) assessing post-operative complications. As with MRI, high quality

CT examinations can be performed in most cases, independent of body habitus. Potentially limiting factors when considering CT include its use of ionizing radiation, with the attendant risks, and iodinated contrast agents, which can induce or exacerbate renal insufficiency and which have a finite risk of allergic reaction. With the substantial benefits of ease of access, extensive clinical utility, and short exam times, the issue of radiation usually only mildly temporizes its routine use—except in studies of pediatric patients and pregnant women.

In recent years, advances primarily in hardware technology have led to dramatic improvements in CT image quality (particularly spatial resolution) while simultaneously reducing overall scan duration. By increasing the number of rows of detector elements in the rotating gantry (from 1, to 4, to 8, to 16, to the new state-of-the-art 64-detector rows), and by increasing the rotational speed of the gantry itself, vendors have now made it possible to image large regions of the body in short periods of time. Combined with ECG-gating, CT with IV contrast can accurately depict cardiac anatomy in a single, short breath-hold. The sub-millimeter spatial resolution of newer generation scanners has made non-invasive, detailed assessment of coronary artery anatomy a reality. Data indicate that with 16-detector row CT scanners, under optimal conditions, high

Table 2. Indications for Cardiac MR.

- Myocardial viability
- Global and regional ventricular function
- Ventricular mass, cavity volumes, and myocardial morphology
- Congenital heart disease before or after surgical repair
- Flow through large vessels and across valves (quantitative)
- Coronary artery anomalies/Bypass graft patency
- Cardiac and extracardiac masses
- Pericardial diseases, e.g. constrictive pericarditis or hematoma
- Cardiomyopathies, including infiltrative processes and those involving the right ventricle such as arrhythmogenic right ventricular dysplasia (ARVD)
- Valvular heart disease
- Diseases of the aorta, such as dissection, aneurysm, and coarctation

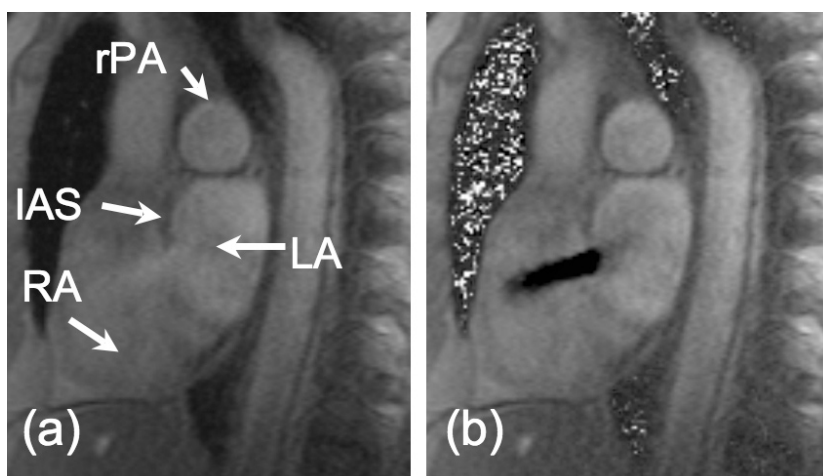


Figure 2. Sagittal MR images of an adult woman with an atrial septal defect. In image (b), flow data superimposed on image (a) confirm significant blood flow from the left atrium (LA) to the right atrium (RA) through the interatrial septum. Note the dilated right pulmonary artery (rPA) secondary to the long-standing shunt.

accuracy can be achieved for the detection of coronary artery stenoses greater than 50%.¹⁰⁻¹² Importantly, in these and numerous other studies relating to CT coronary angiography, the negative predictive value for the presence of coronary atherosclerosis is uniformly very high. While data from the new 64-detector row scanners is still sparse, it seems clear that these scanners will offer considerably improved robustness and reliability, including the promise of more precise gradation of coronary stenoses.

As with MRI, by acquiring data throughout the cardiac cycle, it is again possible to generate movie loops and simultaneously assess cardiac function. The temporal resolution of this technique is poorer than with MRI and detailed wall motion evaluation is not currently possible.

The radiation dose of ECG-gated CT for cardiac imaging is significantly higher than for non-gated studies and probably on par with or slightly greater than that of diagnostic catheter-based coronary angiography.¹³ The appropriateness of use and patient selection criteria will be paramount as this advanced technology percolates into clinical practice. Despite this, the emerging role of CT in cardiac evaluation is undeniable.

The current indications for thoracic cardiovascular CT in the author's opinion are shown in **Table 3**.

SPECIFIC APPLICATIONS OF CCT & CMR FOR SURGICAL PATIENTS

Ischemic heart disease

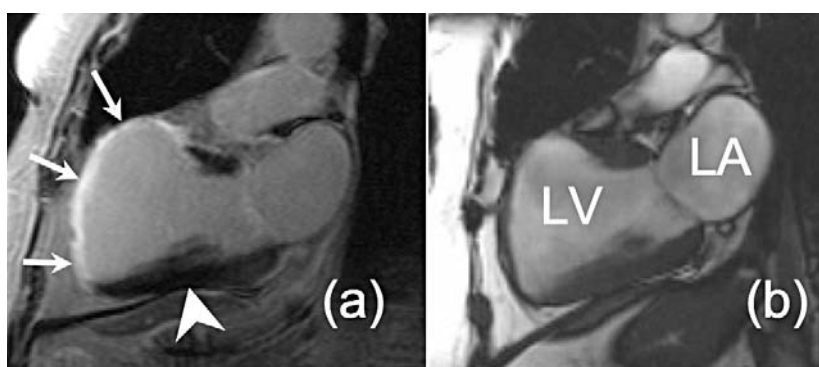


Figure 3. Long axis images of (a) viability and (b) function from a study of a middle aged woman with no prior cardiac history. There is transmurular scar from myocardial infarction in the mid and distal anterior wall and apex (arrows) of the left ventricle (LV). No viable tissue is detected in these aneurysmal segments. The inferior wall (arrowhead) is normal. LA: left atrium.

Table 3. Indications for Cardiac CT.

Non-gated

- 1st line assessment of diseases of the aorta, great vessels & pulmonary vasculature
- Gross evaluation of cardiac and pericardial morphology
- General evaluation of large cardiac and extracardiac masses
- Assessment of thoracic bony structures, mediastinum, and lungs and visualization of various forms of calcification

ECG-gated

- Detailed evaluation of cardiac morphology, pericardium, and cardiac masses
- Global ventricular function
- Coronary artery calcium scoring (non-contrast)
- Coronary artery atherosclerosis imaging (64-detector row CT scanner)
- Coronary artery anomalies/Bypass graft patency
- Detailed aortic root assessment

As mentioned earlier, myocardial viability imaging with MRI accurately delineates scar due to myocardial infarction. The transmural extent of scar is inversely correlated with the likelihood of recovering function following a revascularization procedure, whether it is angioplasty and stenting or coronary bypass surgery. If scar extends entirely across the wall of the heart, for example, then reperfusion alone will not restore function. Conversely, if there is no scar, the chance of establishing some improvement in function is good.

In some settings, extensive myocardial infarction can lead to left ventricular aneurysm formation. (**Figure 3**) Surgical resection of the dyskinetic, dead tissue may be considered (aneurysmectomy). Moreover, if the LV dilates significantly and becomes globular or spherical, some surgeons may attempt to not only exclude the

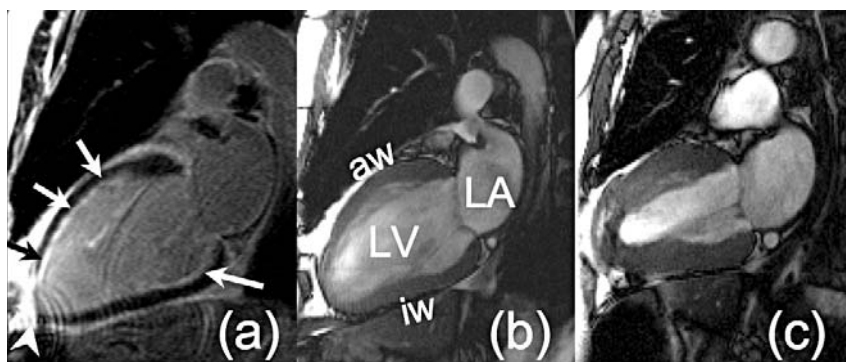


Figure 4. Long axis MR images from a study of a man who underwent ventricular remodeling and coronary bypass surgery. Images (a) and (b) are viability and function images obtained prior to surgery, and image (c) is a function image obtained 3 months after surgery. Function images are at end-systole. In image (a) thin areas of infarction are seen along the anterior (aw) and proximal inferior walls (iw) of the left ventricle (LV) and throughout the apex (arrowhead). The LV was dilated with ejection fraction 24% before surgery. After surgery the EF increased to 56% and chamber size decreased. Note the improved wall thickening of all segments in (c).

dead tissue, but also restore a smaller, more favorable ventricular geometry by inserting a Dacron® patch in the affected portion of the ventricle and over-sewing the scar. The decision to perform this operation is largely determined by the extent of scar and the absolute size of the LV cavity. Because of its ability to simultaneously delineate scar and accurately quantify ventricular volumes, MRI is ideally suited to determine which patients may benefit from this surgery. Representative pre- and post-surgical images from such a case are shown in **Figure 4**. In this case a 3-vessel bypass operation was also performed.

One notable weakness of MRI in the assessment of ischemic heart disease remains accurate coronary angiography. Although techniques can image the coronary arteries with MRI, resolution—for practical purposes—is inadequate to image atherosclerotic plaque and associated luminal narrowing of native vessels. (MRI is reasonably accurate at evaluating bypass graft patency.) MR imaging methods that identify coronary arteries and their proximal trajectories are available and may be useful in the setting of suspected coronary artery anomalies. Nonetheless, contrast enhanced, ECG-gated CT, with its higher spatial resolution, remains the preferred method for evaluating small thoracic vessels, including native coronary arteries and bypass grafts. As stated above, reliable, detailed visualization of obstructive coronary artery disease will likely be realizable with 64-detec-

tor row CT scanners. **Figure 5** demonstrates reconstructed images from a gated CT (16-detector row) study in a patient with internal mammary and venous bypass grafts.

Imaging of perfusion and coronary flow reserve also continues to be a works-in-progress for both MRI and CT. Reliable data on pharmacologic stress perfusion methods are limited, but current CMR techniques may be comparable in accuracy to nuclear methods.¹⁴⁻¹⁶

Congenital Heart Disease (CHD)

Both MRI and CT are well suited to image anatomic abnormalities associated with CHD. When congenital lesions present early in life, the management decisions including surgical palliation or correction may be predicated on clinical presentation, echocardiography, plain films and catheterization findings. Later in adulthood, however, because of normal developmental changes of the thorax, echo may be inadequate for comprehensive evaluation of congenital lesions, whether

found as a new diagnosis or followed from infancy. Here, the volumetric, 3-dimensional nature of both MRI and CT may permit more detailed visualization of the structural abnormalities and post-surgical sequelae (17). MRI further distinguishes itself in its ability to also offer functional information, including segmental and global myocardial contraction as well as quantitative blood flow data. In the setting of an atrial septal defect or an anomalous pulmonary vein, as examples, MRI allows quantitation of the severity of the shunt (i.e. Qp/Qs). Where valve lesions are present, hemodynamic severity can be quantified. Moreover, as patients with CHD are being followed, the changes in both anatomy and function can be monitored in a quantitative manner. While the decision to intervene surgically or percutaneously will still be largely based on clinical grounds, the quantitative data available by MRI can contribute substantially. **Figure 6** shows examples of patent ductus arteriosus by MRI and partial anomalous pulmonary venous return by CT.

Mass

Masses in and around the heart

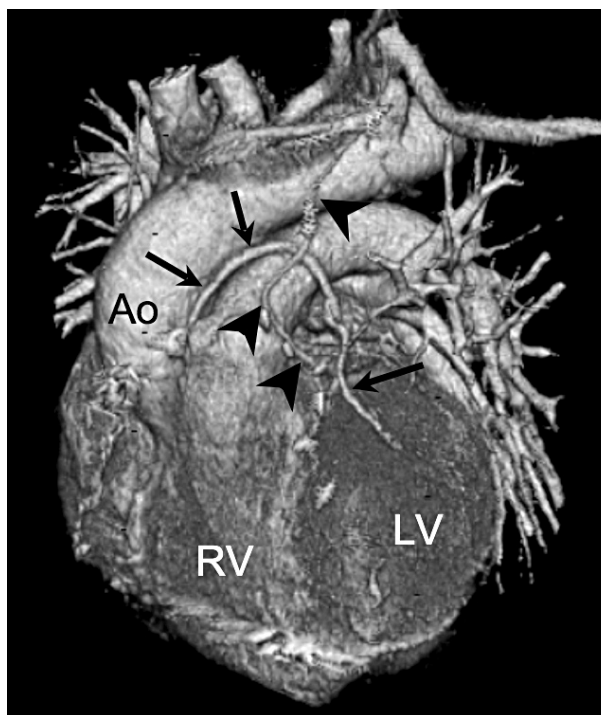


Figure 5. Reformatted image of an ECG-gated CT study on a patient following bypass surgery. The left internal mammary artery (arrowheads) is anastomosed to the left anterior descending (LAD) coronary artery. A vein graft (arrows) arising from the ascending aorta anastomoses to a diagonal branch of the LAD. Ao: aorta; RV/LV: right/left ventricle.

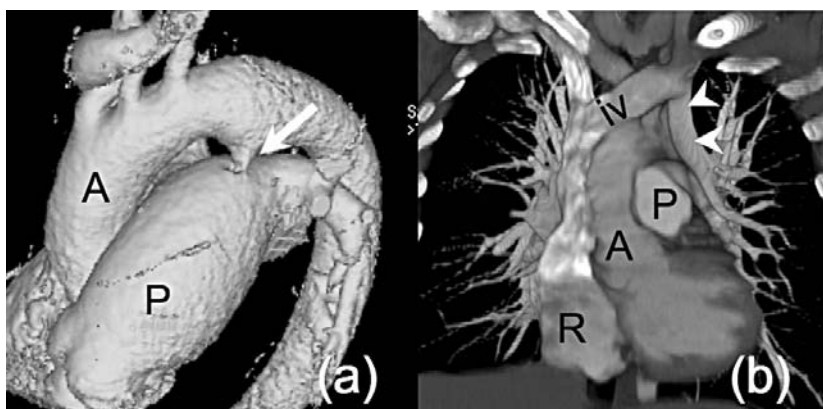


Figure 6. (a) MRI and (b) CT reformatted images of two patients with shunts. Image (a) demonstrates a patent ductus arteriosus (arrow). Image (b) shows an example of partial anomalous pulmonary venous return: the left upper lobe pulmonary vein (arrowhead) drains into the left innominate vein (iv) and NOT the left atrium as it should. In both cases the main pulmonary artery (P) is dilated. A: aorta; R: right atrium.

are often detected incidentally by routine echocardiography or chest CT. If a clear diagnosis can be made—such as a laminated intracavitary thrombus (by echo) or a pericardial cyst (by CT)—then no further evaluation is necessary. Frequently, however, this is not the case and additional characterization is desired. With its broad arsenal of imaging techniques (i.e. pulse sequences), MRI can often narrow the differential possibilities significantly. MRI can readily characterize a mass's size, mobility, site of attachment, and functional significance. Regarding the evaluation of an intracavitary mass, perhaps the most important first step is to determine whether the mass is a tumor or a thrombus. This distinction has significant therapeutic implications. The presence of internal vascularity essentially excludes the diagnosis of thrombus; conversely, the absence of vascularity strongly suggests thrombus. With the aid of intravenous contrast, both CT and MRI are generally able to make this determination. **Figure 7** shows images of a 3 cm right atrial mass incidentally detected in a young woman on dialysis. The absence of post-contrast enhancement on MRI confirmed that this mass was a thrombus that was loosely tethered to the tip of an indwelling catheter. After intracatheter chemical thrombolysis, follow-up echo demonstrated dramatic reduction in mass size (not shown). Cardiac surgery was thus avoided.

Pericardial disease

Many conditions of the pericardium, such as simple and complex effusions, hematoma, masses, and diffuse thickening are generally well imaged by both MRI and CT. With its ability to show motion, MRI also demonstrates how the pericardial disease affects chamber sizes and myocardial function.

The clinical and hemodynamic findings of constrictive pericarditis often overlap substantially with those of restrictive cardiomyopathy. Treatment options for these two conditions are quite disparate, with medical management preferred for restrictive disease (until transplantation becomes necessary) and surgical pericardiectomy of potential benefit for pericardial constriction. Accurate diagnosis is therefore paramount. Pericardial thickening (>4mm) and calcification are

suggestive—but not diagnostic—of constrictive pericarditis and are both readily appreciated on CT imaging. Although MRI is unable to 'see' calcifications, its ability to show anatomy, pericardial thickening, and cardiac function make it very sensitive and specific for the diagnosis of constrictive pericardial disease.

Valvular disease

Direct visualization of cardiac valves is best afforded by echocardiography, with its high spatial resolution and very high temporal resolution. However, MRI does have a useful adjuvant role in its ability to confirm and quantify the severity of various valvular lesions (i.e. pressure gradients, planimetry, and percent regurgitation) and to accurately measure various dimensions pertinent to valve replacement such as valve annulus diameter and aortic root or main pulmonary artery diameter.

Aorta

Major categories of pathology involving the aorta include (1) atherosclerosis, (2) connective tissue disorders such as Marfan's, (3) congenital lesions such as coarctation and vascular rings, (4) large vessel vasculitis such as Takayasu's, and (5) trauma. Complications of these diseases include aneurysm, pseudoaneurysm, intramural hematoma, narrowing, and dissection. Both MRI and CT provide high resolution anatomic imaging important for characterizing mural and morphologic

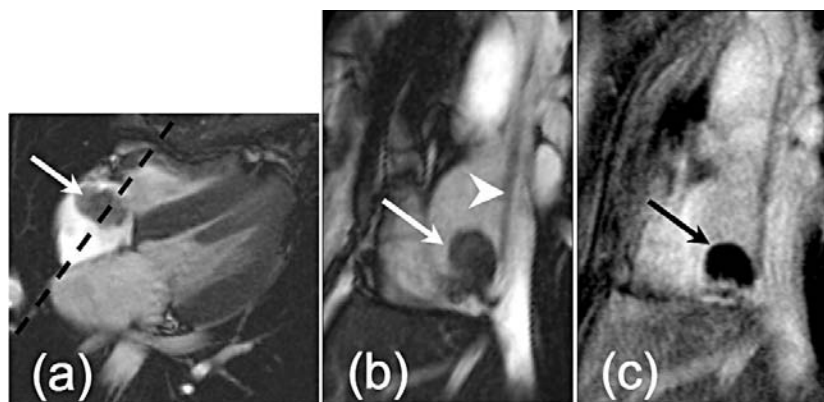


Figure 7. MR images of a 3-cm right atrial mass. (a) 4-chamber and (b) sagittal oblique functional images through the mass (arrows) show that it is loosely associated with a dialysis catheter (arrowhead). (c) Post-contrast imaging demonstrates no evidence of enhancement, confirming that it is a thrombus. The dashed line in (a) indicates the position of images (b) and (c).

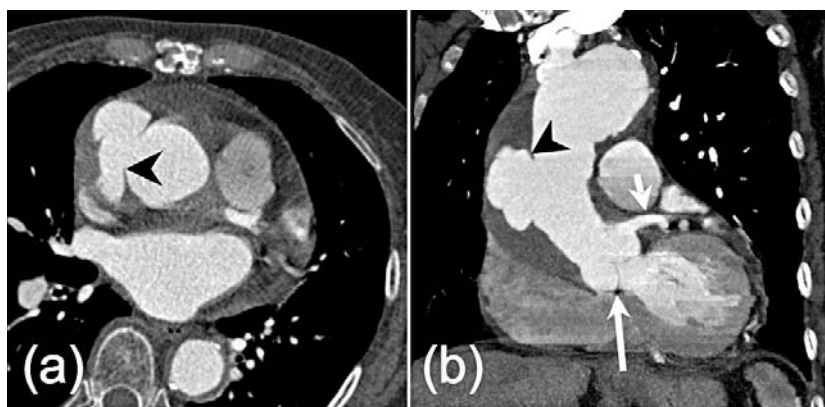


Figure 8. (a) Axial and (b) coronal reformat CT images of a patient with type A aortic dissection and aneurysm. The dissection flap (arrowhead) is readily appreciated in both views. Image (b) also allows visualization of coapted aortic valve leaflets (long arrow) and the patent left main coronary artery (short arrow).

abnormalities. When coupled with IV contrast for lumen evaluation, both modalities provide comprehensive visualization of vascular pathology. With its high accuracy for detecting aortic pathology and its widespread availability, CT easily stands as the first line in the evaluation of suspected aortic injury, particularly in the setting of trauma. **Figure 8** demonstrates ECG-gated CT findings in a patient with type A aortic dissection.

Post-op complications

Both MRI and CT are useful for evaluating post-operative complications associated with cardiovascular surgery, including, mediastinal hematomas, fluid collections, vascular injuries, and infections (e.g. mediastinitis, abscess). In general, CT is superior for assessing bony abnormalities, such as sternal dehiscence, and pulmonary pathology; both MRI and CT are excellent for soft tissue evaluation. ECG-gating is necessary for detailed visualization of cardiac structures.

SUMMARY

Over the last few years, the landscape of cardiovascular imaging has changed significantly. CT and MRI have emerged as robust imaging tools for diagnosing and characterizing a nearly exhaustive spectrum of cardiovascular diseases. With ECG-gating, advanced tomographic imaging techniques are available for imaging the beating heart and surrounding structures with unprecedented accuracy

and precision. These new methods provide clinicians with substantial additional information, including—in the case of MRI—quantitative data on blood flow physiology and accurate measurements of ventricular volumes and function. Importantly, MRI has made recent dramatic strides in the evaluation of ischemic heart disease, and CT appears poised to provide an accurate alternative to catheter angiography in the anatomic assessment of obstructive coronary artery disease. The future of both of these modalities in the non-invasive evaluation of heart disease is bright.

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ADVANCED CARDIAC ANESTHESIA IMAGING TECHNIQUES

ARTHUR A. BERT, MD, AND ANDREW MASLOW, MD

INTRAOPERATIVE TRANSESOPHAGEAL ECHOCARDIOGRAPHIC EVALUATION FOR MITRAL VALVE REPAIR SURGERY

Transesophageal echocardiography (TEE) has become the premier tool in the cardiac anesthesiologist's armamentarium of patient monitoring. The real-time display of detailed cardiac anatomy and in vivo physiology provided by two-dimensional and Doppler techniques has vastly improved the anesthesiologist's diagnostic acumen of ventricular function, valvular disease, intracardiac volume status, and aortic injuries over invasive hemodynamic monitoring. TEE has expanded the anesthesiologist's role during cardiac surgery. More than in any other of the commonly performed cardiac surgeries, advanced TEE skills are required to ably assist the cardiac surgeon in perioperative decision-making during mitral valve repair. Intraoperative TEE assessment of the nature and severity of native **mitral valve (MV)** and subvalvular apparatus disease, and of the post-repair valve function with quantification of any residual regurgitation, iatrogenic stenosis or **left ventricular outflow tract obstruction (LVOTO)**, is essential for successful surgical results, but test the echocardiographer's skills.

MV reconstruction is increasingly favored over replacement with a prosthetic valve for a variety of lesions causing significant **mitral regurgitation (MR)**. Significant advantages of MV repair over replacement include less operative mortality, freedom from long-term potent anticoagulants with reduced risks of thromboembolism and endocarditis, and improved preservation of **left ventricular (LV)** function. It has been suggested that preservation of the mitral valve apparatus (a term describing all the cardiac structures contributing to MV function) architecture results in more favorable LV geometry, reducing post-repair LV wall stress and allowing more favorable remodeling of the ventricle after surgical correction of MR. Whatever the mechanism, conservation of the MV apparatus is associated with a re-

duction of the 5-year mortality after **mitral valve replacement (MVR)** by nearly one-third compared to MVR without preservation of these supporting structures.¹ Preservation of the MV apparatus resulted in significantly higher LV ejection fractions, lower operative mortality, and improved long-term survival in patients with mitral regurgitation treated with valve repair surgery compared to MVR.² Given the high prevalence of ischemic and degenerative MR in the elderly population and the excellent long-term results produced utilizing modern surgical mitral valve repair techniques, more cardiologists are referring patients with the expectation that the MV can be adequately repaired.

Patients presenting for mitral valve surgery have usually undergone a preoperative transthoracic echocardiogram and cardiac catheterization to determine the severity of mitral regurgitation and confirm that surgical correction is needed. This remains necessary since in the surgical suite **general anesthesia (GA)** consistently reduces the severity of MR by lowering preload, decreasing afterload, and depressing the inotropic state of the heart. While these favorable effects of general anesthesia will not significantly alter the severity of MR secondary to a flail leaflet, about 50% of patients with moderate or severe MR on preoperative TEE will demonstrate an improvement of at least one severity grade when assessed under GA.³ The experienced anesthesiologist-echocardiographer will often administer an alpha agonist vasopressor and/or infuse intravenous fluids to induce loading conditions more analogous to the patient's baseline hemodynamic state when there is significant discordance in severity of MR with the preoperative evaluation. Since there are no widely accepted criteria for determining which patients should undergo mitral valve repair versus replacement, the feasibility of repair depends on the pathology of the valve and the skill of the surgeon. A detailed intraoperative TEE evaluation is critical since the etiology of mitral regurgitation, the na-

ture and extent of valve pathology, often predict the likelihood of adequate repair and long-term durability, while the presence of other cardiac pathology (i.e. severe LV wall motion abnormalities or dilated left atrium with thrombus) may significantly influence the surgical plan. For example, the best surgical results are produced in patients with degenerative MV disease (nearly 93% freedom from reoperation at 10 years), while patients with rheumatic MV disease with bileaflet restricted excursion have poor long-term results.^{4,5} Surgeons and anesthesiologists require a commonly understood nomenclature to communicate TEE findings. Most utilize the Carpentier classification system which designates the posterior leaflet, which has well defined anatomic indentations giving it a "three scalloped" structure, as P1, P2, and P3, with P1 the segment adjacent to the anterolateral commissure, P2 the middle scallop, and P3 the segment adjacent to the posteromedial commissure. The corresponding segments of the anterior leaflet, whose segments are anatomically less distinct, are designated as A1, A2, and A3. Pioneer cardiac surgeon Alain Carpentier introduced the concept of "segmental valve analysis" in the surgical planning of MV repair.⁶

Prior to the availability of TEE in surgical suites, cardiac surgeons relied solely on the direct surgical inspection of the MV and the visible subvalvular apparatus to assess the pathology and feasibility for repair. This was accomplished by exposing the valve either during ventricular fibrillation before aortic cross-clamping ("tensed state") or after cross-clamping and cardiac arrest with cardioplegia ("relaxed state"). Either circumstance results in the surgeon examining the mitral valve apparatus in a very non-physiologic state. In an empty, flaccid and rotated heart nearly all leaflet edges can be made to "prolapse" above the mitral annular plane upon nerve hook retraction. The surgeon must assess leaflet segment prolapse or restriction in comparison to a "normal" leaflet segment, which is arbitrarily established as the

P1 scallop. Today surgical inspection remains a valued step in mitral valve repair surgery as it permits confirmation of TEE findings but is recognized as limited especially with regards to subvalvular pathology and prosthetic paravalvular leaks. In the current era of cardiac anesthesia the surgeon expects accurate intraoperative TEE analysis of the mitral valve apparatus in its functional state to facilitate surgical planning

The intraoperative TEE exam must identify the nature of the mitral regurgitation, whether it be from excessive leaflet mobility and prolapse of myxomatous degeneration, restricted leaflet excursion of rheumatic disease, leaflet perforation of endocarditis, or from annular dilatation with normal leaflet motion. Single versus bileaflet valve disease must be determined, and the echocardiographer must correctly indicate the abnormal leaflet, if not the exact scallops involved. Myxomatous degeneration with resultant leaflet prolapse or flail is the most common etiology of MR in patients judged suitable for MV repair. A number of studies^{7,8} have confirmed that an experienced echocardiographer can accurately identify prolapsing MV leaflet segments (90- 97% accuracy with surgical inspection). (Figures 1, 2) These studies have also identified that in patients with myxomatous degeneration presenting for MV surgical repair, isolated posterior leaflet prolapse or

flail (52-70%) is more common than bileaflet and isolated anterior leaflet pathology, while P2 and A2 (>90% and 70% respectively) are the most commonly abnormal scallops. These studies confirm that the P1 scallop, the surgical "normal" reference point, is indeed abnormal in these patients, up to 22% in one series.⁸ TEE studies have confirmed that multiplane probes facilitate the imaging of all individual MV leaflet segments but the numerous intermediary windows available can be confusing and small rotations of the probe can completely change the leaflet segment being imaged.⁸ Since the TEE evaluation of mitral valve occurs while the heart is in its dynamic and physiologic state, the cardiac anesthesiologist has a distinct advantage over direct surgical inspection in identifying the direction of the regurgitant jet with **color flow Doppler (CFD)** techniques. MR jet direction greatly assists in identifying leaflet pathology, as eccentric jets are always directed away from the prolapsing or flail leaflet, but point toward a pathologically restricted leaflet. Centrally directed MR jets suggest either bileaflet dysfunction or normal leaflet motion with dilatation of the MV annulus. This is easily confirmed by TEE measurement of the annulus. Annulus diameters greater than 3.5 cm or 1.7-1.8 cm/m² of body surface area are

considered dilated. While imaging the MV annulus, the extent of annular calcification needs to be reported to the surgeon. Severe annular calcification complicates MV repair or replacement surgery by increasing the risk of ventricular rupture and/or damage to the circumflex coronary artery during debridement, as well as the incidence of prosthetic paravalvular MR.

TEE is an ideal imaging modality for assessment of the subvalvular apparatus pathology inclusive of the chordae tendineae, papillary muscles and supporting LV walls, which are often not available for surgical inspection especially in cases of difficult mitral valve exposure. Chordal laxity or frank chordal rupture resulting in a flail leaflet is common with degenerative disease. Ischemic MR is mostly due to papillary muscle dysfunction ranging from thickening (fibrosis) and/or calcification of the chordae to frank papillary muscle rupture (most often the posteromedial muscle), and alteration in LV geometry. Left ventricular wall motion abnormalities, the presence of a dilated LV cavity with apical or posterior displacement of the papillary muscles must be identified. The surgeon must weigh all these TEE findings with his technical skills, the individual patient's clinical situation and our current knowledge of predictors of successful MV repair. Omran et al⁷ in their prospective analysis of 170 patients undergoing MV repair reported that a central MR jet (bileaflet disease), severe mitral annular calcification, dilatation of the annulus (>5cm) and three or more diseased leaflet segments were independent predictors of a failed repair. Isolated posterior leaflet prolapse has the greatest success rate. Anterior leaflet repair is technically more demanding, often requiring chordal reconstruction or transfer, and is more likely to be associated with residual MR and reoperation.² Rheumatic leaflet disease is judged repairable only when fibrosis and calcification of the leaflets and subvalvular apparatus is minimal, and restriction of leaflet excursion minimal. With severe rheumatic valvular disease and restricted bileaflet motion as little as 20% of patients have adequate repairs.

The intraoperative post-repair TEE exam evaluates the functional status of the reconstructed MV and

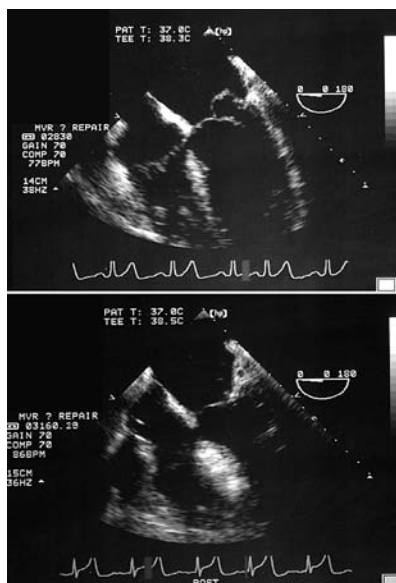


Figure 1:
Isolated posterior leaflet prolapse
a) Pre-repair
b) Post-repair

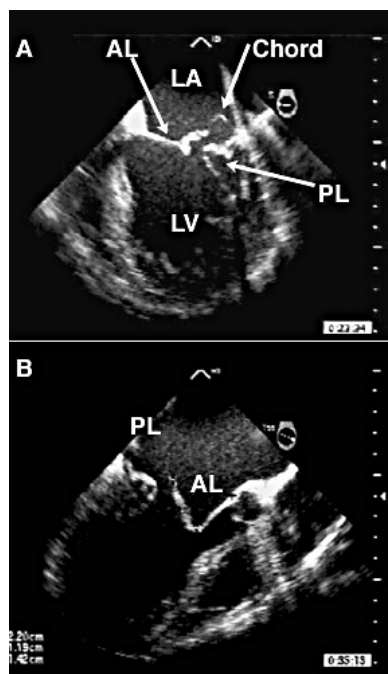


Figure 2: Bi-leaflet disease with flail anterior leaflet demonstrating torn chords in left atrium

offers the surgeon an immediate opportunity to re-repair or replace the valve as needed to ensure good long-term valve function. The goal of valve repair is to restore valve function, rather than correct anatomy. Most repair techniques include resection of abnormal posterior leaflets and repair of anterior leaflets, chordal reconstruction and reductive annuloplasty via implantation of a flexible or rigid prosthetic ring. These techniques result in a functionally “unicuspid” MV where the residual posterior leaflet acts as a buttress to keep the mobile anterior leaflet from prolapsing into the left atrium. Prior to TEE availability, the adequacy of surgical repair was evaluated by filling the arrested ventricle with saline through the reconstructed MV and inspecting for atrial leakage. The intraoperative TEE exam utilizes 2D, color flow and spectral Doppler imaging to assess adequate leaflet coaptation and valve integrity while detecting surgically created stenosis. Immediate failures of repaired mitral valves are detected in 8-9% of patients by intraoperative TEE.^{7,9} Immediate failure after MV repair is most commonly due to **left ventricular outflow tract obstruction (LVOTO)**, incomplete repair of the pathology, or suture dehiscence. Saiki et al¹⁰ demonstrated that the intraoperative TEE quantification of any residual MR significantly correlates with early (median 15 days) and late (median 16 months) postoperative transthoracic echo assessment of MR. This study also reported that nearly half of 42 patients assessed to have no valve leakage in the “fluid-filled” test had residual MR, six of whom required further surgical repair. Post repair MR of mild (1+) or moderate (2+) increases the incidence of late reoperation threefold in comparison with no or trace MR¹¹ but did not result in an increase in long-term mortality.¹² While any residual MR quantified as 2+ or greater is now considered an inadequate repair, the decision to reintervene in the presence of mild (1+) residual MR must take into account the condition of the heart, the potential injury a second ischemic cross-clamp period may induce, and the likelihood of successful re-repair versus replacement.

MV repair with reduction annuloplasty produces a narrower valve orifice. Post-repair mean transvalvular

gradients >7 mmHg are of concern and suggest significant stenosis. However since the circulation is frequently hyperdynamic in the early post cardiopulmonary bypass period resulting in increased transvalvular gradients, measurement of the **mitral valve area (MVA)** is a more reliable assessment of potential iatrogenic mitral stenosis. MVA is determined either by planimetry (the transgastric short axis view), or by the pressure half time methodology. MVA of 1.5 cm² or less represents significant stenosis.

Systolic anterior motion of the MV (**SAM**) with LVOTO is a known complication of MV repair and must be ruled out as a cause of post-repair residual MR and/or low cardiac output. The mechanism of SAM with LVOTO is multifactorial, but most of the data identify excess mitral leaflet tissue as the major cause. Maslow and colleagues¹³ used pre-repair measurements of the mitral valve apparatus to predict patients with myxomatous valve disease at higher risk of post-repair SAM and LVOTO. The incidence of post-repair SAM and LVOTO was greater in patients with excessive posterior leaflet length in relation to the anterior leaflet (AL/PL ratio < 1 versus > 3) and smaller pre-repair distance from the leaflet coaptation point to the ventricular septum (<2.5 cm). The identification of high risk patients for SAM and LVOTO alerts the surgeon to utilize a repair technique that moves the post-repair coaptation point more posteriorly, such as the Carpentier “sliding posterior leaflet” technique, which significantly reduces the occurrence of SAM.¹⁴ TEE evaluation will promptly identify SAM and

LVOTO post-repair.(Figure 3) If 2D imaging identifies any portion of the mitral valve apparatus in the LVOT, color flow Doppler will confirm if turbulent flow is occurring in the LVOT. SAM with LVOTO commonly results in post-repair MR with a posteriorly directed jet, readily identified by CFD. Spectral Doppler can measure pressure gradients across the LVOT. The severity of LVOTO is dynamic in this clinical situation, and the presence of inotropic drug infusions, vasodilators and/or hypovolemia will either induce or exacerbate SAM and LVOTO. The cardiac anesthesiologist is obligated to alter the hemodynamic conditions when SAM with LVOTO is identified post- MV repair prior to declaring surgical repair unsuccessful. Discontinuation of inotropes and volume loading or even the administration of beta-blockers has been reported to resolve LVOTO.¹⁵ If these maneuvers fail and SAM with LVOTO persists, surgical reintervention is necessary.

Post-repair TEE evaluation of the heart in its dynamic and physiologic state has become the new gold standard in determining the adequacy of MV repair surgery. The anesthesiologist- echocardiographer must be willing and capable to become involved in the perioperative decision making process with the surgeon.

ADULT CONGENITAL HEART DISEASE

Once confined to sub-specialists in pediatric cardiology, the increased understanding of **congenital heart disease (CHD)** has advanced surgical corrective and palliative treatments, extending the lifespan of children with

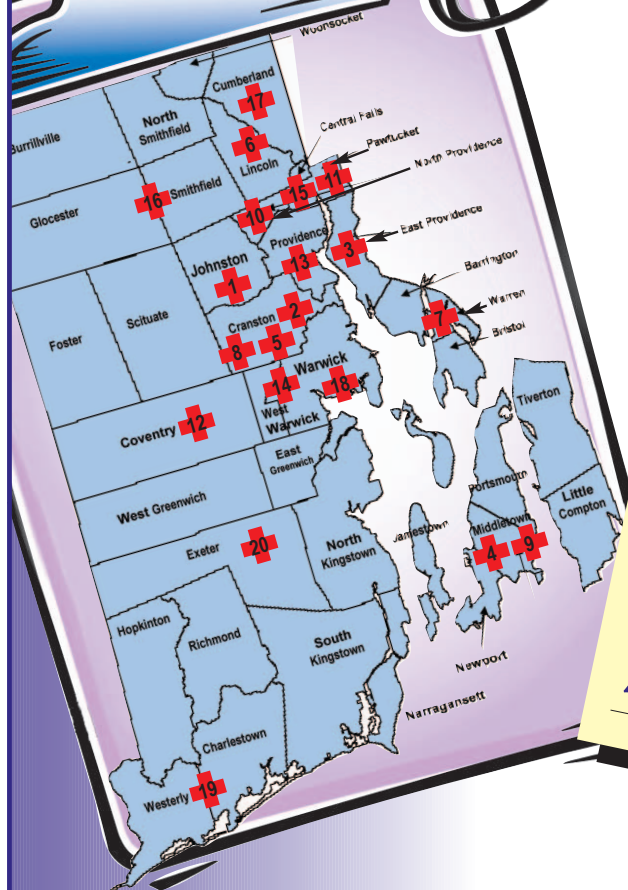
Table 1: Congenital Heart Anomalies Presenting During Adulthood

Atrial Septal Defect (secundum, primum, sinus venosus)
Ventricular Septal Defect
Patent Ductus Arteriosus
Aortic Coarctation
Tetralogy of Fallot
Tricuspid Atresia
Aortic Valve Stenosis
Pulmonary Artery Stenosis
Pulmonic Valve Atresia or Stenosis
Right Ventricular Outflow Tract Obstruction
Corrected Transposition
Ebstein's Anomaly
Congenital Coronary Artery Anomaly (LAD from RCA; RCA from LAD or LCX)
Anomalous Hepatic Vein or Vena Caval Inflow
Eisenmenger Syndrome



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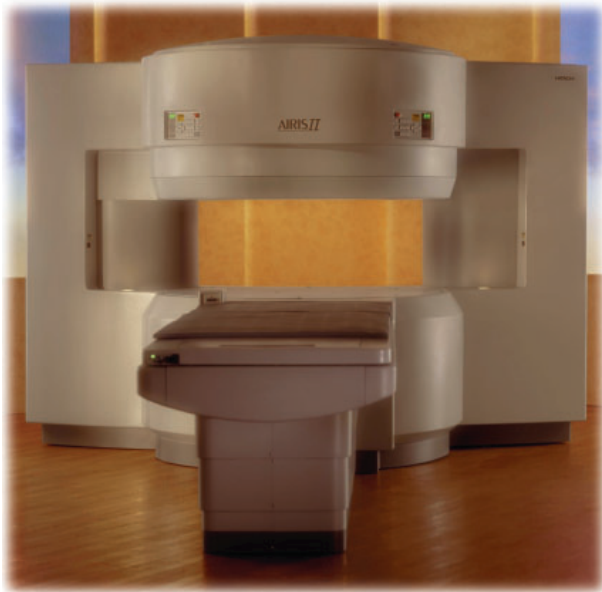
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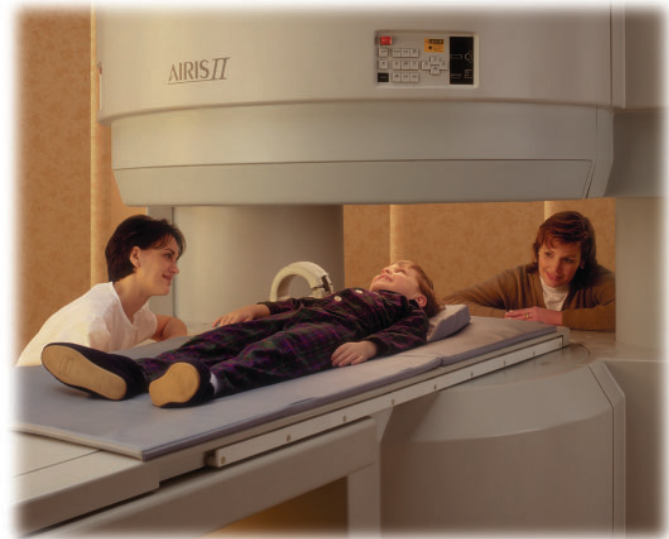
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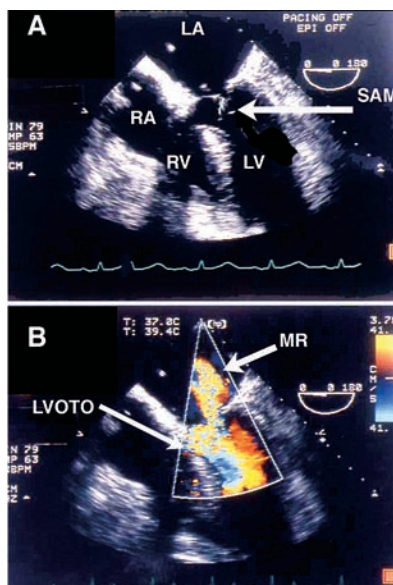


Figure 3: SAM/LVOTO
 a) 2D image demonstrates mitral valve apparatus in LV outflow tract
 b) CFD reveals turbulent blood flow in LVOT and posteriorly directed mitral regurgitation jet

complex cardiac lesions, making it likely that most cardiac surgical programs will encounter these patients. An estimated 85% of pediatric patients with CHD survive to adulthood. The population of **adults with CHD (ACHD)** in the US now exceeds that of children with heart disease, estimated at more than one million.¹⁶ This growing population of patients has prompted the establishment of ACHD programs at many tertiary cardiac centers.

ACHD are often more complex than infants due to the diverse underlying pathology, residual defects from prior surgery, and in some instances from the multi-organ dysfunction due to long-standing hypoxemia or cyanosis. Only a small fraction of CHD is surgically “cured” in terms of no continuing cardiac needs with little chance of a residual defect or complication. These are simple atrial septal defect closures, ligation of patent ductus arteriosus, or coarctation repairs. In the 1980s most surgical procedures for CHD were palliative and many of these patients have been lost to follow-up from the tertiary care pediatric institution that originally provided care. Now they are presenting at adult institutions with the long-term cardiac sequelae of persistent residual lesions.¹⁷

Lesions in ACHD are myriad, ranging from simple to complex .

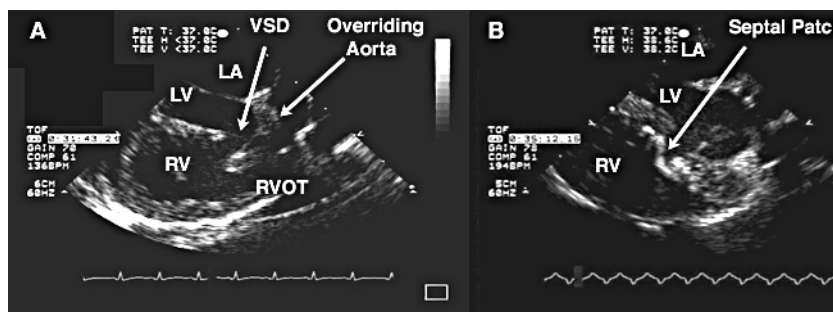


Figure 4: Tetralogy of Fallot anatomy
 a) Pre-repair
 b) Post repair

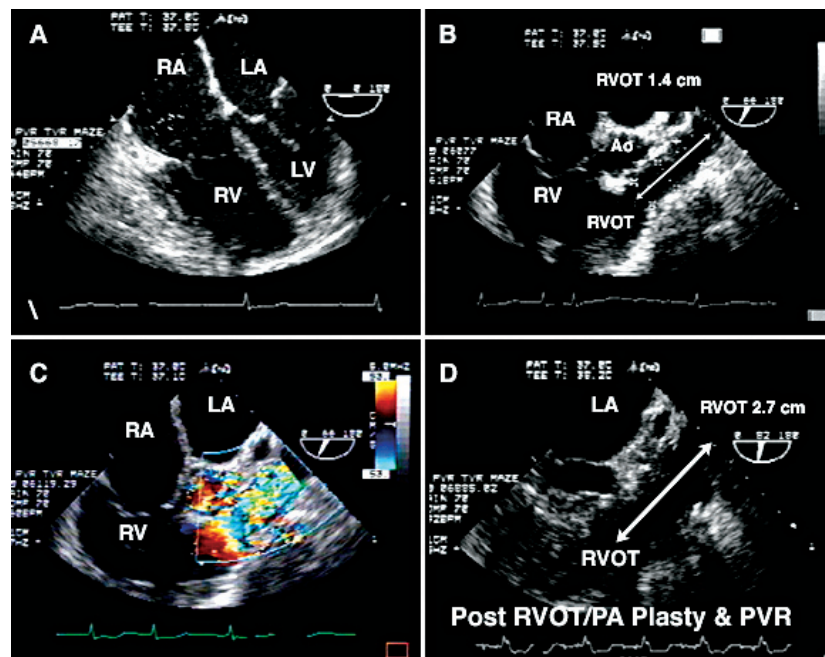


Figure 5: Tetralogy of Fallot with prior repair demonstrating:
 a) Dilated RV and tricuspid valve annulus
 b) Long area of RVOT stenosis in the *in situ* homograft
 c) CFD revealing turbulent blood flow along RVOT stenosis
 d) Post repair homograft with enlarged RVOT diameter



Figure 6: Tetralogy of Fallot with prior homograft with no remaining pulmonic valve
 a) CFO demonstrating severe pulmonary regurgitation
 b) Pre redo repair dilated RV

(Table 1) The objectives for the anesthesiologist- echocardiographer performing intraoperative TEE include defining the primary pathology, identification of associated defects, evaluation of hemodynamics and bi-ventricular function, and detection of any residual pathology or iatrogenic defects from prior surgery. Advancements in imaging technology have fa-

cilitated our collective diagnostic abilities, and allowed clinicians to follow serial changes in heart function and cardiac dimensions with time. While magnetic resonance imaging is considered the gold standard for measurement of right heart volumes and aortic abnormalities, echocardiography remains the primary preoperative and intraoperative technology of choice.

Simpler and milder CHD not diagnosed until adulthood include atrial septal defects, small ventricular septal defects, bicuspid aortic valve disease, and coarctation of the aorta. After correction of the previously undiagnosed CHD, the most common surgery for ACHD is a reoperation to repair a previous surgical treatment of CHD. Most common of these reoperations involve patients with Tetralogy of Fallot.

Tetralogy of Fallot is the commonest cyanotic congenital heart lesion and makes up approximately 10% of all CHD. The constellation of defects includes **right ventricular outflow tract obstruction (RVOTO)**, an overriding aorta (receives blood from both ventricles), a **ventricular septal defect (VSD)**, and right ventricular hypertrophy. (Figure 4) The anatomic spectrum is diverse and can include varying degrees of hypoplasia of the pulmonary arteries or pulmonary atresia. The primary pathology is the displacement of infundibular septum resulting in a mal-alignment VSD, narrowing of the RVOT and aortic override. Signs and symptoms in TOF are the result of "dynamic" RVOT obstruction leading to a reduction in pulmonary blood flow and, under certain circumstances, severe right to left shunting and cyanosis. In the past most cyanotic children with TOF were palliated with a systemic to pulmonary artery shunt (most commonly utilizing the subclavian artery, a Blalock-Taussig shunt). The current surgical practice in a child without severe cyanosis or "Tet spells" is to perform a "definitive" repair early, usually by 6 months of age. The feasibility of repair depends, to a large part, on the development of the proximal pulmonary arterial tree, and the pulmonary valve, and the ability to resect sub-pulmonary valve infundibular tissue in the RVOT. Correction of TOF involves patch closure of the VSD, usually via a right ventriculotomy, and relief of the RVOTO. The latter often involves resection of infundibulum, enlargement of the pulmonic valve annulus with a transannular patch, or when TOF occurs with an atretic pulmonic valve or pulmonary artery hypoplasia, a RV-PA homograft conduit is utilized. Current operative mortality is approximately 2% and twenty-year survivals exceed 90%, after these type repairs.

But the heart is not "normal" in the overwhelming majority of these patients. By the third decade after surgical repair, TOF survivors have reduced exercise tolerance and are at particularly high risk of sudden death.¹⁸ This is related to the chronic pulmonary insufficiency from transannular patching which renders the native pulmonary valve incompetent leading to RV dilatation and malignant arrhythmias.

Although our clinical experience has included the full spectrum of primary atrial septal defects, congenital ventricular septal defects, aortic valve anomalies, we are increasing caring for ACHD patients with prior surgical repairs, of which patients with TOF are the most common. With survival to adulthood, a host of long-term sequelae increase the likelihood of reoperation during early adulthood. These include recurrence of RVOT stenosis, pulmonary artery stenosis, severe pulmonary insufficiency (Figures 5,6), aortic dilatation, aortic valve insufficiency, residual septal defects, and resultant tricuspid regurgitation. Over half the patients with prior Tetralogy of Fallot repairs, present for conduit replacement for severe regurgitation or conduit stenosis, often from calcification of the homograft.¹⁹ Intraoperative TEE must define the site of recurrent RVOT obstruction, confirm the pulmonic valve function or lack thereof, evaluate RV function, and exclude other pathology or residual defects. Since most of these patients underwent initial surgical treatment in an era prior to intraoperative TEE, many present with an identifiable perimembranous residual VSD. Residual VSD are extremely difficult for the surgeon to identify in the arrested heart, so it is essential that the intraoperative TEE confirm both the location and post-repair closure. Reoperations for these patients are complicated by the adversities of any redo cardiac surgical procedure (bleeding, worsening degrees of cardiac function), as well as the sequelae of the residual defects of TOF, the most significant of which are RV dysfunction with limited reserve systolic function and malignant ventricular arrhythmias. Data support vigilant follow-up and assessment after the initial surgery, and early reoperation to prevent long-term right heart failure.²⁰

Echocardiography remains the

best non- or semi-invasive tool for the assessment of cardiac function in patients with CHD, treated or not. With a well-established adult congenital heart disease clinic, follow-up and reoperation for progression of residual pathophysiology can be properly timed and patient outcome can be optimize. Late reoperation increases the risk of irreversible right heart failure, a condition made transiently worse after use of cardiopulmonary bypass and cardioplegic arrest. While the future direction for care of CHD includes the development of a biologic pulmonary artery conduit/valve that will grow with the patient, permitting a 'definitive' correction of TOF, for now cardiac anesthesiologists must use perioperative TEE to facilitate repair operations.

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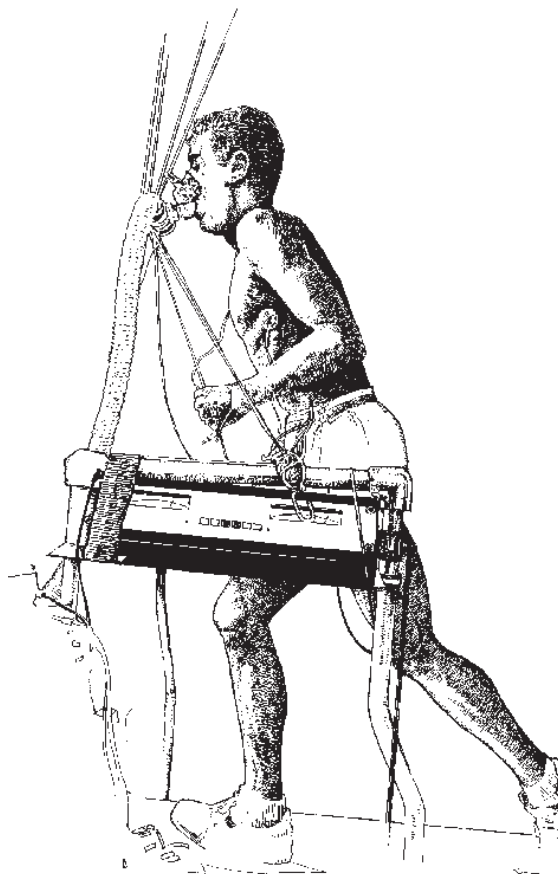


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BEATING HEART SURGERY

R. ERIC LILLY, MD

Coronary artery bypass grafting (CABG) remains the most common heart operation with over 300,000 procedures performed annually in the United States.¹ Inherent to the successful widespread acceptance of surgical coronary arterial revascularization was the introduction of Gibbon's heart lung machine in 1966. Since then, **cardiopulmonary bypass (CPB)** has been applied routinely. Recently coronary surgical efforts have been refocused towards less-invasive procedures including a move away from routine use of CPB for CABG with operations performed on the beating heart. Mid-term data including randomized trials have examined these newer procedures both in terms of coronary graft patency and in terms of complications when compared to conventional CABG with CPB. Results from these studies are mixed. This paper will review the status of surgical coronary revascularization and examine the controversy surrounding routine use of "beating-heart" CABG.

CONVENTIONAL CORONARY ARTERY BYPASS SURGERY

The overwhelming majority of CABG procedures in the United States and Canada are still performed on an arrested heart while the patient is supported by CPB.² The process of initiating CPB requires that the patient be anticoagulated, usually with heparin, and that the ascending aorta be extensively manipulated. Aortic manipulation is often extreme with placement of an arterial cannula in the ascending aorta for return of oxygenated blood from the CPB circuit, crushing the ascending aorta by cross-clamping, and performing often multiple arteriotomies for suturing the proximal anastomoses for the coronary bypass grafts. While on CPB,

the patients' platelets adhere to the circuit, inflammatory mediators become activated and coagulation factors are diluted, all leading to often a severe coagulopathy and deleterious systemic inflammatory effects.³ Arterial cannulation is most commonly performed in the in the ascending aorta prior to the origin of the great vessels. Atheromatous plaque from the aorta or debris from the CPB circuit may embolize distally with resultant stroke or end-organ dysfunction. Despite these potential deleterious affects, CPB remains safe for most patients as evidenced by reported mortality and stroke rates in the 1-3% range.

Reliance on CPB, however, has traditionally limited the possibility for surgical revascularization in many patients with significant co-morbidities. Severe atherosclerotic changes in the ascending aorta are associated with unacceptably high stroke and mortality rates when routine CPB is applied.⁴ Additionally, patients with severe pulmonary disease or recent stroke also exhibit unacceptable clinical outcomes. These patients have remained essentially unserved by conventional CABG.

"THE USE OF OFF-PUMP CORONARY SURGERY HAS SOARED IN THE UNITED STATES OVER THE PAST 7 YEARS."

BEATING HEART SURGERY

To serve high-risk patients with surgical coronary revascularization and to make CABG surgery less invasive, the trend in cardiac surgery has been away from routine use of CPB in CABG

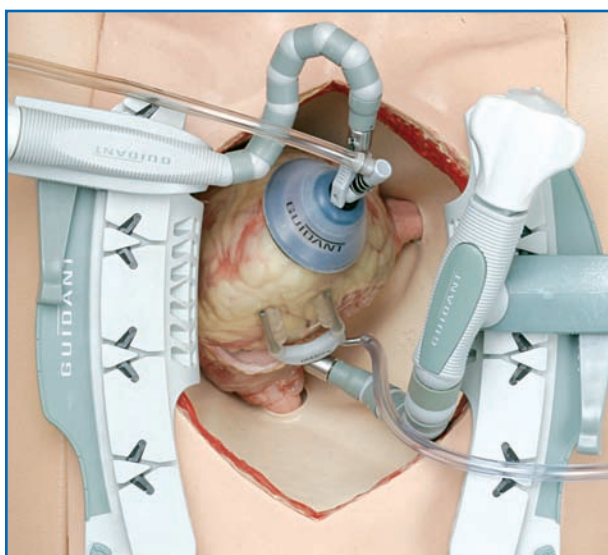


Figure 1: Guidant® Stabilization System for beating heart surgery.



Figure 2: Guidant® Heart String device for clampless coronary anastomoses.

and toward decreased manipulation of the ascending aorta. The use of **off-pump coronary surgery (OPCAB)** has soared in the United States over the past 7 years. Some centers perform CABG exclusively off-pump on the beating heart. Nationwide, 25% of all CABGs are performed without CPB.

CABG performed on the beating heart is an old procedure: the first reported procedure occurred in St Petersburg, Russia, in 1964.⁵ This technique has been and remains the standard operation for surgical coronary revascularization in developing countries as reported by many series published throughout the 1990's.⁶⁻⁸ The routine use of OPCAB in these countries is less about patient outcomes and more about the relative high cost of the CPB circuit.

In the United States, industry-driven technological advancement of off-pump surgical equipment has in large part driven the popularity of this technique. Suction devices that are applied to the epicardial surface allow easy manipulation of the heart and acceptable surgical exposure to all coronary artery distributions without compromising the patients' hemodynamics. Additional stabilization devices are applied to the epicardium around the target coronary vessel requiring surgical bypass that create a relatively motionless field thereby allowing successful coronary anastomoses. (Figure 1)

Two basic techniques for beating heart surgical revascularization have gained acceptance. Mid-CAB is a procedure that employs a left anterior thoracotomy through which the **left internal mammary artery (LIMA)** is taken down from the chest wall. Commercially available retractors facilitate the LIMA harvest. The pericardium is then opened overlying the **left anterior descending coronary artery (LAD)** and the LIMA to the LAD anastomosis is performed on the beating heart with the aid of a stabilizer. The Mid-CAB approach is typically limited to a single LAD-LIMA anastomosis and therefore is reserved for patients with left anterior descending coronary artery disease only. This technique has been unpopular, in part because of the pain associated with a thoracotomy which is often significantly greater than that of a full sternotomy, and because of the rarity of single vessel LAD disease patients being referred for surgical revascularization.

Most patients referred for CABG have multivessel and often complex coronary artery disease. The beating heart technique designed to serve these patients has been termed OPCAB. This procedure involves a standard mid-line chest incision with a complete sternotomy. Patients are heparinized with generally half the dose required for CPB. Both pleural spaces are widely opened to facilitate displacement of the heart within the chest cavity allowing exposure of all coronary artery distributions without kinking of the great vessels or compression of the right ventricle as the heart is manipulated. Stabilizers are utilized to facilitate the coronary anastomoses which are performed on the beating heart. A bloodless field is accomplished with the aid of a carbon dioxide/saline mister to irrigate the field,

silastic tapes placed around the artery to control blood loss, and often intra-coronary shunts which are removed prior to completion of the anastomosis. A period of regional heart ischemia is induced as the vessel being bypassed is occluded. Patients are monitored with SVO2 Swan-Ganz catheters and trans-esophageal echocardiography to assess regional heart function. The OPCAB procedure is the most commonly performed beating heart surgery.

The principal advantage of OPCAB is the avoidance of CPB. To accomplish coronary bypass grafts, ascending aortic arteriotomies are generally required. Historically these anastomoses are facilitated by placement of a partial occlusion clamp on the side of the ascending aorta. This clamp crushes the aorta and therefore allows for the possibility of atheromatous plaque to be dislodged and embolize distally. New devices have become commercially available that allow coronary grafts to be anastomosed to the ascending aorta without these crushing clamps. These devices have included the St Jude Symmetry Aortic Connector and the Guidant Heart String device. (Figure 2) The full benefits of OPCAB versus conventional CABG for reduction of post-operative complications depend on this clamp-less approach.

RESULTS

The most common complication of conventional CABG is the occurrence of atrial fibrillation.⁹ Post-operative length of stay is generally prolonged and marked hemodynamic consequences can occur particularly in patients with baseline marginal left ventricular function. Extensive effort has been applied to the understanding and prevention of atrial fibrillation in conventional CABG resulting in the routine clinical use of beta-Blockers and careful attention to electrolyte shifts in the post-operative setting. Despite all clinical efforts, the reported incidence of atrial fibrillation remains as high as 40% in some series.⁹ Advanced patient age is the most commonly associated factor for its occurrence.

A recent meta-analysis of observational studies sought to examine the potential benefit of OPCAB for prevention of atrial fibrillation when compared to conventional CABG in older patients.¹⁰ Eight observational studies performed in patients greater than 70 years of age published between 1999 and 2003 were evaluated. These included 3017 patients of whom 764 underwent OPCAB and 2253 conventional CABG. The overall incidence of atrial fibrillation was 22% in the OPCAB group versus 28% in the conventional CABG group. These data translated into a significant, albeit small, reduction in atrial fibrillation in OPCAB using the random effect model. The authors postulate that a diminished inflammatory response and decreased global myocardial as well as atrial injury during OPCAB versus conventional CABG likely contribute to this risk reduction.

Multiple trials have addressed the question of whether all coronary revascularization surgery should be done routinely without the assistance of CPB. A meta-analysis of 18 randomized studies comparing routine coronary surgery versus OPCAB published prior to August 2003¹¹ examined

the combined end-point of mortality, stroke and myocardial infarction in 1584 patients of which 783 were randomized to OPCAB and 801 to conventional CABG. The use of OPCAB in these patients reduced the relative risk of this combined end-point by 27% at 2 weeks, 25% at 1 month, 45% at 3 months and 34% at 1 year. None of these reductions reached statistical significance secondary to the relatively small number of events noted. An additional five randomized trials in 2004 included an additional 1,164 patients.¹² These studies reported an occurrence of the same combined end-point as above (i.e., mortality, stroke and myocardial infarction) to be 2.9% in the on-pump CABG group as compared to 3.9% in the OPCAB group.

Additional data examining the routine use of on-pump CABG versus conventional CABG have been derived from the New York State Cardiac Reporting System.¹³ Between 1997 and 2000, 9,135 patients underwent OPCAB, compared to 59,044 who underwent conventional CABG in New York State. Risk adjusted mortality was 2.02% for OPCAB as compared to 2.16% for conventional CABG ($p=0.390$). Patients with surgery performed off-pump exhibited lower post-operative lengths of stay (5 vs. 6 days, $p<0.001$), decreased rates of perioperative stroke (1.6 vs. 2.0%, $p=0.003$), and decreased rates of reoperations for post-operative bleeding (1.6% vs. 2.2%, $p<0.001$). Higher rates of gastrointestinal bleeding, perforation or infarction occurred in the OPCAB group versus the on-pump group (1.2% vs. 0.9%, $p=0.003$). Three-year survival and the need for subsequent revascularization procedures were also examined. On-pump patients exhibited a higher freedom from death or subsequent revascularization procedures compared to the OPCAB group (adjusted risk ratio = 1.232, $p<0.001$). These three-year follow-up data were unexpected. The authors postulated that these results are likely secondary to a steep learning curve for OPCAB as compared to conventional CABG. This postulate has been reflected in other reports with other authors suggesting equivalent results in OPCAB as compared to conventional CABG only after the surgeon has performed in excess of 200 off-pump CABG's.¹⁴ These data have yet to be confirmed in a large randomized trial.

Inherent to successful coronary artery bypass surgery is the patency of the bypass grafts. An important randomized trial in 2004 compared the two surgical strategies in terms of bypass graft patency. This was a single center and single surgeon trial.¹⁵ A total of 200 consecutive patients were randomized either to conventional on-pump CABG or to OPCAB regardless of their coronary anatomy or left ventricular function. Post-operatively, patients underwent coronary angiography prior to discharge from the hospital and at 1-year of follow-up. Patients with severe atherosclerosis or renal insufficiency were excluded from angiography. Prior to discharge from the hospital, 93.4% of patients underwent angiography with graft patency of 99% for OPCAB patients as compared to 97.7% for conventional CABG. Coronary angiography was again performed at 1-year. At this time, 93.6% of grafts were patent in the

OPCAB group, as compared to 95.8% in the conventional CABG group. Neither of these differences reached statistical significance. Additionally, no difference was found between the groups in the incidence of death, myocardial infarction, stroke, recurrent angina, readmission for cardiac events or need for post-operative percutaneous intervention.

A second randomized trial again examined graft patency at an intermediate-term follow-up.¹⁶ This study randomized 104 patients to either OPCAB or conventional CABG. Postoperative coronary angiography was performed at 3 months. In the conventional CABG group 127 of 130 grafts (98%) were patent as compared to 114 of 130 grafts (88%) patent in the OPCAB group ($p=0.002$).

These studies, while small, have called into question the routine use of OPCAB for surgical coronary revascularization. The potential benefits of OPCAB which include a diminished rate of perioperative atrial fibrillation, a small but diminished stroke risk and diminished perioperative bleeding appear to be off-set by an increased risk of gastrointestinal complications and a significantly decreased long-term graft patency and patient survival. Routine application of off-pump CABG as a replacement for on-pump conventional CABG is obviously in question. The Veterans Affairs **Outcomes Following Myocardial Revascularization: On and Off Cardiopulmonary Bypass (ROOBY)** study which is accruing patients will likely illuminate this controversy.¹²

As evidenced by this discussion, a controversy exists within the surgical community surrounding the routine use of off-pump techniques for coronary revascularization in low-risk patients. There is no controversy, however, concerning application of these techniques to high-risk patients. The use of CPB clearly predisposes all patients to some element of lung injury as manifested by reductions in FEV_1 and increased oxygen requirements in post-CPB patients. These changes may render marginal patients ventilator dependent. The OPCAB technique has been shown to attenuate this reduction in lung function.¹⁷ OPCAB has also been associated with a decreased need for blood transfusions compared to conventional CABG.¹¹ As such, OPCAB should be applied to patients with blood dyscrasias or in those whom blood transfusion is not an option (e.g., Jehovah's Witness).

Patients who most clearly benefit from OPCAB, compared to conventional CABG, are those with severe atherosclerotic changes of the ascending aorta in whom use of CPB is not possible or associated with an unacceptably high stroke risk.⁴ Clinical trials have generally excluded patients with severe atherosclerotic changes in their aortas, given this high stroke risk. While these high-risk patients may benefit from OPCAB, there remains a defined risk of stroke even in typical patients undergoing CABG without severe atherosclerotic changes of the aorta. The most surprising result from the randomized trials has been the lack of a significantly greater stroke risk reduction in patents performed off-pump as compared to those in whom conventional CPB was utilized. The absence of a greater reduction is likely

attributable to the lack of routine use of clamp-less CABG in these trials. Broad application of clamp-less techniques for coronary anastomoses such as afforded by the Guidant Heart String device likely will further reduce stroke in OPCAB patients.

Patients with recent stroke often exhibit worsening neurologic status when routine cardiopulmonary bypass is applied. Diminished cerebral autoregulation after stroke, non-pulsatile flow during CPB and the potential conversion to a hemorrhagic stroke secondary to the extreme heparinization required for CPB all contribute to these potential neurologic changes. The general practice is to reserve CPB in stroke patients until six weeks have elapsed after their event. OPCAB revascularization is a valuable strategy for these high-risk patients.

FUTURE DIRECTION

Refinements in surgical revascularization will rely on techniques that allow CABG to be performed on the beating heart without the necessity of a sternotomy. This may be accomplished using an approach similar to the Mid-CAB technique except that both the right and left internal mammary arteries are harvested from the chest wall employing bilateral thoroscopic incisions. Coronary anastomoses may then be performed under direct vision or with the aid of robotic technology. The principle advantage of this technique is that both internal mammary arteries may be harvested without incising the sternum, compromising the blood supply to the sternum, and thereby increasing the risk of mediastinitis. While use of bilateral IMAs has been demonstrated to add a survival benefit to patients undergoing CABG,¹⁸ routine use is generally avoided in obese or diabetic patients because of a marked increased risk of infectious complications in these patients in particular. Further refinements in robotic technology will be required prior to widespread acceptance of this technique.

SUMMARY

Off-pump beating heart coronary revascularization is a valuable surgical technique for high-risk patients, particularly those with severe atherosclerotic changes of the aorta, COPD, recent stroke, or for those in whom blood administration is contraindicated. Advances in clampless surgical techniques should further the benefit of OPCAB versus conventional CABG mostly in terms of stroke risk reduction. For now, routine use of OPCAB for all surgical revascularization procedures remains in question.

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ATRIAL FIBRILLATION FROM A SURGICAL PERSPECTIVE

GEORGE N. COOPER, JR, MD

For over 20 years I have witnessed the ravages of atrial fibrillation (AF) as a frequent, sometimes lethal, postoperative complication. Warfarin is one of the mainstays of AF treatment and reduces the incidence of AF-related strokes.^{1,2} Until recent, AF has been an irrevocable life sentence.

Major hemorrhages with Warfarin have occurred at an annual rate of 10% in a subgroup over age 75.³ In a large series in Wales,⁴ patients treated with Warfarin were outside the INR target range 32% to 71% of the time. Time spent outside the target range decreased from 52% initially to 30% after two years. This still leaves many patients at risk for embolism or hemorrhage.

AF is the most common of all sustained cardiac arrhythmias: the prevalence increases with age up to 5% in persons older than 65; and it is a major cause of stroke.⁵ Other literature shows AF in 8%-17% of the population over age 60.⁶

AF affects 2.5 million patients in the United States, with 300,000 new cases diagnosed every year. The risk of stroke in patients with AF is estimated at four times greater than in patients without AF. AF is second to heart failure in terms of cardiac-related hospitalizations.

The prevalence of thromboembolism associated with AF is roughly 33% (825,000 United States citizens).⁷ Approximately 75% of all thromboembolic episodes associated with AF involve the brain (608,000 U.S. citizens). In one series, 60% of cerebroembolic events resulted in death or permanent, severe neurologic deficit (364,950 U.S. citizens).⁷

In the late 1980s, Dr. James Cox and colleagues in St. Louis identified the electrical characteristics and sites of AF in animals and patients.⁶ This made possible the development of surgical treatments to prevent the abnormal atrial conduction pathways, which cause this arrhythmia. Dr. Cox developed an operation by which multiple, full thickness incisions were made in both atria to interrupt the abnormal macro-circuits. The left atrial appendage was excised as well, thereby removing the major source of cerebral and peripheral emboli. All of these incisions were then closed by suturing. The result was the Cox "Maze III" operation for AF. If done correctly, the mortality rate was and is low and success in curing AF is still over 93% with no recurrences over 14 years in the original St. Louis series of patients.⁸ Other series had similar results.^{9,10}

In spite of the success of this concept, the "Maze" was not appealing to heart surgeons because it was a very difficult art form with every suture line a possible bleeding complication. Maze operations needed significant heart-lung machine time and had a steep learning curve. Some centers persisted nevertheless and noted a marked reduction in postoperative stroke rate and increased freedom from AF.^{11,12}

Since the late 1990s there has been a resurgence of interest in surgery for AF. Technological advances have made it possible to apply all of the Cox described ablative lesions in a matter of minutes with radiofrequency, cryotherapy or microwave energy with the same effect as the "cut and sew" method, thus avoiding the necessity of multiple atrial incisions and resuturing which commonly took about one to one and a half hours.¹³

In the recent three to four years, based on laboratory and clinical series,^{14,15} it has been demonstrated that it is not necessary to perform all of the Cox described atrial ablative lesions to cure atrial fibrillation and that only a basic set of left sided ablations could still accomplish over 90% success and be easily applied even without the help of the heart-lung machine. If necessary, additional right-sided lesions could easily be performed in the electrophysiology laboratory.^{16,17}

Haissaguerre in 1998,¹ working in Bordeaux, studied 45 patients, mapping the spontaneous initiation of atrial fibrillation. 69 foci were identified and 65 (94%) were found originating in the pulmonary veins. The pulmonary veins have been targeted, therefore, by electrophysiologists and surgeons working on this problem. Surgeons in many centers, including our own, have been ablating the left atrium adjacent to the entrance of the pulmonary veins and removing the left atrial appendage in each instance. These ablations are usually done with a bipolar radiofrequency device in conjunction with valve or coronary bypass operations. The results are very promising. Over 157 Maze operations have been done in Rhode Island since 2000 by seven heart surgeons. All of these have been carried out in conjunction with operations for other cardiac pathology, including mitral and/or aortic operations, with or without coronary bypass. Initially most of our Maze attempts sought to include all or most of the Cox described ablative lesions on left and right atria. Many times, however, based on various series in the literature,^{14,15} only left-sided lesions were done, especially if the patient was having an off pump operation; e.g., off pump coronary bypass. There are very few patients in the Rhode Island series who have had Maze procedures who are not free from atrial fibrillation. The exact numbers will be the subject of a follow-up article in this journal.

Recent technological development has included minimally invasive surgical approaches to pulmonary vein-left atrial ablation. These involve bipolar radiofrequency, laser¹⁸ and microwave technologies.^{19,20} The bipolar radiofrequency device has been easy to use and yields full thickness atrial wall ablation, which completely blocks the pulmonary vein foci from causing AF. Also included in this concept is the denervation, or obliteration, of multiple ganglionic plexi which are numerous and located on and around the pulmonary veins. The importance of this is alluded to by Schuessler, Boineau and Cox who, in 1991,²¹ discussed atrial fibrillation occurring after bradycardia induced by

acetylcholine infusion or vagal stimulation. Also, Coumel²² showed that patients with high vagal tone have spontaneous atrial fibrillation associated with increased vagal activity. Scherlag in Oklahoma²³ reported in 2005 that stimulating the autonomic ganglia at the right superior pulmonary vein in dogs provided a substrate for conversion into atrial fibrillation. Thus, in addition to atrial ablation at the entrance of pulmonary veins, it becomes important to ablate also the ganglionic plexi. This denervation concept is emphasized by Dr. Randall Wolf at the University of Cincinnati. Dr. Wolf's minimally invasive approach consists of bilateral two and a half inch transverse incisions in the anterior axillary line, entering the chest through the third or fourth intercostal space with no rib spreading, thus no or very little discomfort. A double lumen endotracheal tube is used, allowing selective deflation of the lung on the operative side. First the right side is done, then the patient is turned and positioned with the left side up so that the left sided portion of the procedure can be completed. This concept provides good visualization of pulmonary veins and vena cavae on the right and pulmonary veins and left atrial appendage on the left. Visualization and illumination are aided by a camera port lower down on the chest and one additional port for the radiofrequency device. Most of the work is done through the two and a half inch incisions. After the ablations are completed and the pulmonary veins are electrically isolated, the left atrial appendage is removed or stapled out with the endo-GIA automatic stapling device. Pain has been minimal and hospital stay has been two to three days in Dr. Wolf's series. Fig 1 shows the extent of the left chest incision after completion of bilateral ablation. In the past 20 months Dr. Wolf has performed the "mini-Maze" in nearly 100 patients.²⁴ All of the patients who presented with paroxysmal atrial fibrillation are in sinus rhythm postoperatively. The patients with permanent atrial fibrillation have taken a bit longer to convert, but they seem to eventually achieve normal



Figure 1: This picture illustrates the closed 2" incision in the left anterior axillary line just lateral to the nipple and below the axillary hair stubble. A small silastic chest tube has been placed in the port site originally occupied by the thoracoscope. There is a similar incision on the right side. There is no rib spreading. Intercostal blocks with 0.5% bupivacaine are routinely done prior to closure.

rhythm.²⁵ In the beginning of the Cincinnati experience, the intention was to do a mini-Maze only on patients with paroxysmal atrial fibrillation, but patients with permanent atrial fibrillation were referred in significant numbers, so these were added to the mix. In the September, 2005 issue of *The Journal of Thoracic and Cardiovascular Surgery*,²⁶ Dr. Wolf et al reported on 27 patients (22 male patients) with atrial fibrillation (18 paroxysmal, 4 persistent and 5 permanent; over age 57 years). All underwent the above described bilateral video-assisted thorascopic off-pump epicardial radio frequency pulmonary vein isolation and stapler exclusion of the left atrial appendage. The operation was performed successfully in all patients. There were no conversions to sternotomy or thoracotomy. All patients were extubated in the operating room. The average postoperative follow-up was 6 months (173.6 days). 23 patients were followed for more than 3 months, and 21 of these were free of atrial fibrillation (91.3%). Magnetic resonance angiography showed no pulmonary vein stenosis in 12 of 12 patients evaluated by this technique 3-6 months postoperatively. The general observation has been that if the left atrium is normal in size or only slightly enlarged, the chances of success with the mini-Maze in permanent atrial fibrillation are good, although it may take three or four months for conversion to sinus rhythm to occur. If the atrium is 6 cm or larger, the patient may be better served with a formal open heart Maze operation with reduction of left atrial size by resecting a strip of left atrial wall in the posterior aspect, which if needed, is very easily accomplished. The long-term results of the mini-Maze in permanent atrial fibrillation remain to be delineated, but the initial observations are causing some optimism.

We have begun the minimally invasive AF surgery program at Miriam Hospital. Two patients have successfully completed the operation. One spontaneously converted to sinus rhythm 3 weeks postoperatively and the second is in sinus rhythm after cardioversion 6 weeks post-operatively. Many of the patients will take 4-8 weeks to regain sinus rhythm. Dr. Wolf cautions that a 3-month wait may be necessary before normal sinus rhythm is achieved. The Wolf mini-Maze concept has significant promise and is associated with a hospital stay of only two to three days as compared to five to seven days with the conventional Maze operation. We are very excited to offer this technology to AF patients in Rhode Island whose lives have been seriously altered by this arrhythmia.

Indeed, as the evolution continues, AF may cease to be a life sentence. The Maze operation and possibly the minimally invasive Maze offer great hope of restoring life without AF or Warfarin, with virtually no surgical mortality and minimal morbidity.

SUMMARY

Before 1985, there was no surgical solution for AF. Any therapy contained uncertainties and Warfarin was still needed in the treatment regimen. The Maze operation as described by Dr. Cox cures AF. Recent modifications in technique and technology have allowed us to apply Dr. Cox's concepts in

ways that are easy to apply surgically with excellent results and virtually no mortality and minimal morbidity. In most cases Warfarin will become unnecessary, the number of strokes will be markedly reduced and normal lifestyle can be restored. The minimally invasive Maze procedure is very appealing. It is an atrial ablation as well as cardiac denervation. It is user-friendly, so far effective and associated with minimal discomfort and short hospitalization.

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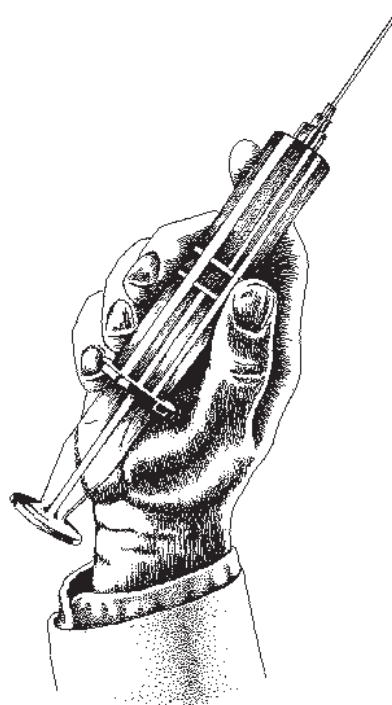
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LEFT VENTRICULAR REMODELING OR RESTORATION FOR CONGESTIVE HEART FAILURE

GEORGE N. COOPER, JR, MD

Congestive heart failure affects five million people in the United States. This disease is manifested by loss of the normal elliptical ventricular architecture to produce a dilated spherical ventricle with limited contractile and filling capacities.¹ Among the five million, 70% have coronary artery disease. Of these, 90% have had a myocardial infarction resulting in loss of regional contraction and altered cardiac structure/function relationship. In an anterior infarction, there is loss of the anterior free wall and adjacent septum. There is conversion of the normal elliptical shape with oblique fiber orientation (where 15% shortening causes 60% ejection fraction) to a spherical chamber where a more transverse fiber orientation reduces contractile forces (i.e., 15% fiber shortening causes 30% ejection fraction) in remote viable muscle.² (Figure 1)

With revascularization or valve replacement therapy, survival is reduced when starting and ending with ventricles having reduced ejection fraction or increased ventricular volumes.^{3,4,8}

Progressive dilatation of muscle remote from an infarct reduces its contractile force and increases congestive heart failure and mortality, depending on ultimate ventricular size.⁵ Ventricular volume is important in determining prognosis. HD White⁶ showed in 1987 that left ventricular end systolic volume is the major determinant of survival after recovery from myocardial infarction. (Figure 2) End systolic volume is a better predictor of survival than ejection fraction. In White's study, patients who died had higher end systolic volumes for a given ejection fraction than those who survived. Migrino, et al⁷ in 1997 showed that **left ventricular end systolic volume index (LVESVI)**, measured 90 to 180 minutes into reperfusion therapy, was a strong predictor of mortality. Even if assessed at a time remote from an acute episode, a resting LVESVI of more than 60 ml per meter squared, reflects a threshold likely to be associated with subsequent cardiac mortality. (Table 1)

Yamaguchi³ showed a significantly better survival in patients having coronary bypass with preopera-

tive LVESVI of less than 100 ml/m² compared with those with preoperative LVESVI greater than 100 ml/m². (Figure 3) In spite of ample demonstration of the importance of LVESVI, the concept continues to be, in large part, under-utilized.¹ LVESVI can best be measured by cardiac MRI, which also can determine where the infarct is, how much myocardial thickness is involved, how much of the septum is

“VENTRICULAR RESTORATION RESULTS IN IMMEDIATE IMPROVEMENT IN SIZE AND FUNCTION AND WHEN ADDED TO REVASCULARIZATION, HAS MARKEDLY IMPROVED SURVIVAL AND FREEDOM FROM CONGESTIVE HEART FAILURE.”

involved, exact ejection fraction and which areas of the myocardium are still working. In hearts with reduced function, the MRI can tell us if ventricular remodeling or restoration is likely to be successful. If end systolic volume index can be restored to a reasonably normal range, prognosis can be improved.^{8,9,10}

Surgeons in several other large centers¹⁰ advanced the concept of restoring the elliptical ventricular shape so that once again the oblique cardiac muscle fibers could generate a more normal ejection fraction.^{10,12,13} In 2004, a report on 439 ventricular restoration cases documented a LVESVI decrease from 80.4 preoperatively to 56.6 postoperatively. Ejection fraction increased from 29.6% preoperatively to 39.5% postoperatively. Five-year freedom from hospital admission for congestive heart failure was 78%.

Maxey et al⁸ in 2004 reported on 95 patients, 39 of whom had coronary bypass alone and 56 had ventricular restoration with coronary bypass. Ventricular restoration yielded significant and immediate improvement in ejection fraction compared with coronary bypass alone. In this series of patients with large ventricles, morbidity and mortality were significantly reduced if ventricular restoration accompanied coronary bypass. There were no deaths in either group; however, late mortality was higher in the coronary bypass alone group. Freedom from heart failure was achieved in all but two of the ventricular restoration plus coronary bypass group (2 of 56) versus 7 of 39 in the coronary bypass group.

Patients are candidates for ventricular restoration if they have had an anterior myocardial infarction, have a large area of akinesis or dyskinesis, may or may not yet have clinical evidence of heart failure and probably are candidates for myocardial revascularization.⁹ Contraindications include loss of function at the base of the

TABLE 1. Relationship Between ESVI and Adverse Outcomes

ESVI, mL/m ²	n	Congestive Heart Failure, %	Shock, %	Reinfarction, %	30-d Mortality, %	1-y Mortality, %±SEM
<10	44	2	0	0	0	0±0
10 to <20	357	10	3.4	2.8	2.2	3.1±0.9
20 to <30	410	12	4.6	3.4	3.9	5.4±1.1
30 to <40	268	13	6.3	3.4	4.5	6.4±1.5
40 to <50	110	16	8.2	7.3	10.0	15.7±3.5
50 to <60	52	19	11.8	5.8	15.4	21.2±5.7
≥60	59	31	15.3	8.5	20.3	32.5±6.1

Based on Kaplan-Meier estimates.

Table 1 A high end systolic volume index, (ESVI), was associated with increased 30 day and 1 year post MI mortality, as well as with increased in-hospital events, (Shock, congestive heart failure and reinfarction).

From: Migrino et al. *Circulation*, 96:116, 1997. With permission.

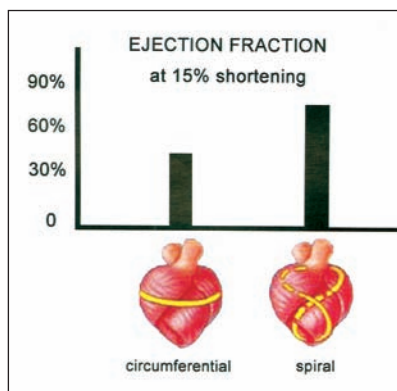


Figure 1 Relationships between fiber orientation and ejection fraction with 15% muscle shortening. The circumferential fibers of the band muscle loop have a 30% ejection fraction. The helical apical vortex has a 60% ejection fraction. When the apical fibers dilate post MI, they develop a more transverse muscle orientation, losing the oblique normal pattern, resulting in a diminished ejection fraction.

From: Buckberg et al. *Seminars in Thoracic and Cardiovascular Surgery*, 13:358, Oct. 2001. With permission.

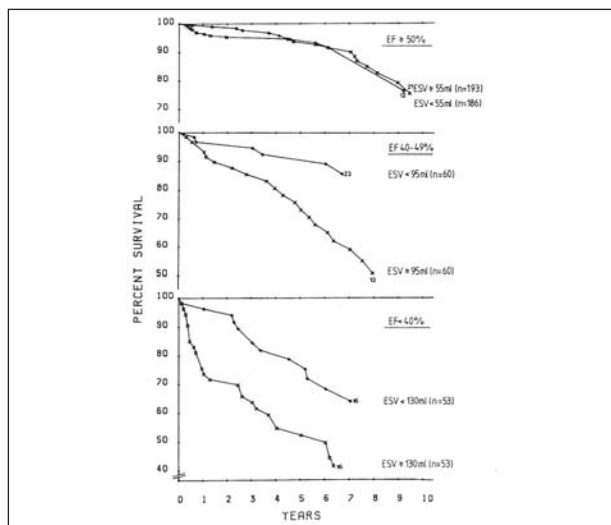


Figure 2 For patients with ejection fraction under 50%, survival was significantly worse when end systolic volume (ESV) was above the median for that group than it was when ESV was below the median value. For individual patient

s, ESV varied widely for the same ejection fraction, with the higher ESV patients having much shorter survival. From: White HD et al. *Circulation* 76:44, 1987. With permission.

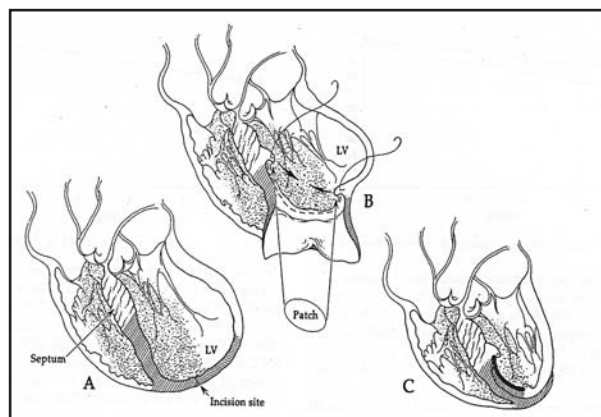


Figure 4 (A) Anterior incision into dilated scarred ventricle after antero-septal infarction. The anterior wall and septum need to be excluded from the circulation by a patch.

(B) Encircling suture at junction of good muscle and scar to prepare for a patch

(C) Completed repair with Endocardial patch and infarcted thinned out muscle closed over patch.

From: Athanasuleas CL et al. *JACC* 44:1439. With permission.

heart, pulmonary hypertension, and right ventricular dysfunction.

Typically in patients with large ventricles post myocardial infarction, the ventricular septum is involved in the enlargement process. This is seen on cardiac MRI in which the non-functional infarcted septum is very amply delineated so that one can see how much needs to be excluded in order to return the ventricle to a smaller, elliptical configuration. In the past, the primary approach to the ventricle was to resect only obvious aneurysms with a bulging segment.¹¹ These were usually identified by venting the ventricle while on cardiopulmonary bypass, thus revealing the collapsed free

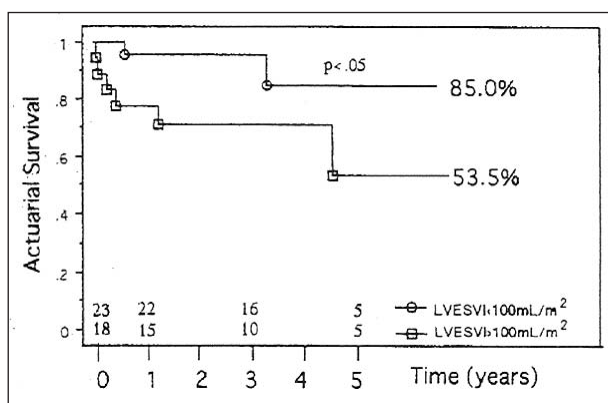


Figure 3 Actuarial survival curve from Yamaguchi's group of 4 coronary bypass patients with preoperative ejection fraction below 30%. The survival rate during follow-up for patients who had a preoperative left ventricular end systolic volume index (LVESVI) of less than 100 ml/m² was significantly greater than that for patients who had a preoperative LVESVI of greater than 100 ml/m².

From: Yamaguchi A. *Annals of Thoracic Surgery* 65:434, 1998. With permission.

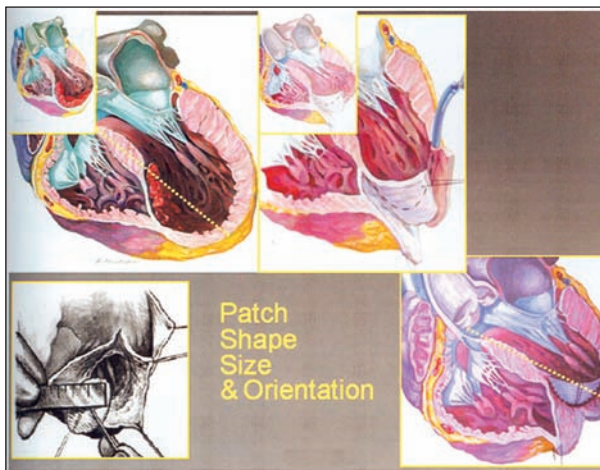


Figure 5 The proper orientation of the endoventricular patch is parallel to the septum, thus changing a spherical shaped ventricle to the normal elliptical configuration. If the patch is inadvertently placed in the same plane as the mitral valve, it will tend to distract the papillary muscles with resultant postoperative mitral regurgitation.

From: Dor V et al. *Seminars in Thoracic and Cardiovascular Surgery* 13:435, 2001. With permission.

left ventricular wall, which was then opened, and closed longitudinally in an attempt to reduce ventricular size. This did very little to change ventricular size or shape because the bulging septum was left unaltered.

In Figures 4 and 5, one can see a patch remodeling the ventricle, excluding infarcted and useless septum, excluding thinned out anterior wall and changing a big, baggy ventricle into a normally configured, smaller left ventricular cavity. It is important to exclude septum. The septum cannot be resected and if infarcted, contributes significantly to the inefficient spherical ventricular shape. After patch placement, the excluded anterior heart wall is sutured or imbricated over the patch. A very functional elliptical ventricular shape results with a normal LVESVI and normal prognosis in terms of ventricular size.⁶

I have been applying the ventricular restoration concept in the recent 24 months. The last four patients all had anterior myocardial infarctions and needed revascularization. The ejection fraction in each case was around 20%. Instead of proceeding immediately to the operating room, cardiac MRI's were obtained. The **left ventricular end systolic volume indices (LVESVI's)** were markedly increased. Infarcted areas were identified and a reconstructive plan configured. Myocardial revascularization was carried out, but with the addition of ventricular restoration. The ejection fractions increased to 33, 34, 56 and 40% respectively. A more recent fifth patient increased his ejection fraction from 18% to 29%. Only one patient showed any symptoms of postoperative heart failure and he received a combination biventricular pacer/defibrillator. All patients are fully functional at this time and not in heart failure. All of the ventricles returned to more normal shape and compared to the pre-operative status were much more efficient. Often there is a certain amount of mitral regurgitation associated with post myocardial infarction ventricular dilatation. When concomitant mitral repair was necessary, it was successfully accomplished from the intraventricular approach before completing the ventricular restoration surgery.

A new and valuable tool in the treatment of ischemic cardiomyopathy is in our midst. Instead of proceeding

hurriedly with coronary revascularization alone, then progressive ventricular dilatation, followed by heart failure, followed by the almost automatic or knee jerk response of defibrillator or biventricular pacemaker, one can redirect the scenario from the beginning. If one has a post myocardial infarction patient with reduced ventricular function and indications for revascularization, then one should obtain an MRI, look at the ventricular function and geometry and decide whether ventricular restoration is feasible. If restoration accompanies coronary bypass, the overall prognosis will, in all likelihood, be significantly improved.^{8,9} In my personal series, this has been the case.

Not all cases are straightforward. It has been found useful to discuss some potential restoration candidates with a heart failure team to determine where they are in the spectrum of being potential candidates for cardiac transplantation or possibly postoperative ventricular assist devices. These adjuncts could then be implemented as needed with full knowledge of the possibilities beforehand. So far, no assist devices have been necessary.

Ventricular restoration is becoming more widely applied in the treatment of ischemic cardiomyopathy and should significantly diminish subsequent admissions for heart failure, as well as numbers of post myocardial infarction patients on disability. Ventricular restoration could mean restoration to normal life.

SUMMARY

Large numbers of people have anterior myocardial infarctions, many in mid-life, with progressive left ventricular dilatation and heart failure with diminished life expectancy. Myocardial revascularization alone helps ischemia, but does little in cases of large ventricular volume, which is the major determinant of post infarction mortality. Ventricular restoration results in immediate improvement in size and function and when added to revascularization, has markedly improved survival and freedom from congestive heart failure. When coronary bypass is being considered after anterior infarction or in patients with reduced ventricular function, MRI to determine function and viability is recommended. Then a valid, informed judgment can be made about patch reconstruc-

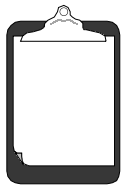
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PUBLIC HEALTH BRIEFING

RHODE ISLAND DEPARTMENT OF HEALTH

DAVID GIFFORD, MD, MPH, ACTING DIRECTOR OF HEALTH

EDITED BY JOHN P. FULTON

MEDICARE PRESCRIPTION DRUG PLANS: THE IMPACT ON PHYSICIAN PRACTICE

SHARON MARABLE, MD, MPH

The implementation of the new Medicare Prescription Drug Coverage program has been promoted as the greatest thing that has happened in Medicare since President Lyndon Baines Johnson signed this program into law. Although physicians and other health professionals are not expected to become Medicare counselors, there are steps you can take to prepare for the onslaught. Are you ready?

BACKGROUND

Your patients with Medicare have the opportunity to enroll in Medicare's voluntary prescription drug plan coverage which activates on January 1, 2006.¹ In the standard Prescription Drug Plan benefit, the enrollee pays an average monthly premium of \$32.00, the first \$250.00 of annual drug costs deductible, and 25% of the cost of prescriptions from \$251-\$2,250. From \$2,251 through \$5,100, or the drug coverage gap, the beneficiary pays the entire cost of their medications. Once the beneficiary spends \$3,600 out-of-pocket, Medicare pays 95% of the prescription drug costs.²

In Rhode Island, there are eighteen health insurance plans offering over forty-four **prescription drug plan (PDP)** options. Several plans omit the \$250.00 deductible and a few offer additional assistance during the drug coverage gap.³ The formularies of each PDP include a percentage of the top 100 medications prescribed to seniors from the Medicare Drug Card experience.⁴ Each plan is required to cover "all or substantially all" medications in the antidepressant, antipsychotic, anticonvulsant, immunosuppressant, HIV/AIDS and cancer treatment categories. Furthermore, the Medicare Prescription Drug Plans cover brand name and generic medications available by prescription, insulin, and medical supplies associated with the injection of insulin.² However, an individual PDP formulary might not encompass all the medications a senior takes on a daily basis. Please note, some of the health plans with more than one

level of Prescription Drug Plan have a different formulary for each drug plan product. Categories of medications excluded from Medicare prescription drug coverage include medications for relief of cough & colds, non-prescription drugs, barbiturates, benzodiazepines or drugs paid for under Medicare Parts A or B.²

IMPLICATIONS FOR MEDICAL PRACTICE

The Medicare Part D program has a huge impact on the clinical practice of medicine. As patients enroll in these PDPs, medical providers in private practice and nursing homes will be faced with the task of switching patients over to specific medications listed in the patients' new PDP formulary. This will be a challenging task given the volume of elders enrolling in Prescription Drug Plans within the enrollment period, coupled with the care a clinician must take to taper a fragile elder off one medication to another and monitor for side effects simultaneously. Moreover, the physician with a patient enrolled in a Medicare PDP might be involved in the prescription drug plan appeals process in circumstances when a non-formulary drug is medically necessary or when a patient requires a medicine suddenly removed from the PDP formulary.²

As clinicians face the potential burden of more prescription writing and a bevy of formularies to familiarize themselves with during the Drug Plan transition, it is critical that providers have access to accurate PDP formulary information. At some point, the **Centers for Medicare & Medicaid Services (CMS)** plans to post all of the PDP formularies on its website and include them in programs designed for PDA devices.⁵ In the meantime, please check <http://www.health.ri.gov/medicare> for Rhode Island PDP formulary information. Additionally, the Medicare PDPs are required to support e-prescribing capabilities, with pilot testing to begin later in the year.⁶

The influx of PDP coverage in

Rhode Island will add another layer of chronic disease management and quality improvement monitoring to office practice. Eventually, each PDP will roll out a Medication Therapy Management Program which will focus on patients with multiple chronic illnesses, on multiple medications or likely to incur at least \$4,000 in prescription drug costs in one year. Program details are pending at the time of publication. There are also plans for monitoring items such as the use of selected medications within certain therapeutic categories and drug-disease interactions.⁶

STRATEGY TO RESPOND

Several Rhode Island medical societies and academies have posted Medicare PDP information online. Please go to your academy or medical society website for provider-related information on Medicare PDP coverage. The **Rhode Island Department of Health (HEALTH)** Medicare PDP website at <http://www.health.ri.gov/medicare> builds upon the educational efforts within the medical community. This site will provide formularies for the local PDPs as CMS approves these website postings, and have support materials for providers who manage the health care for special populations, such as HIV/AIDS patients.

If a patient asks you for information about PDP coverage, please refer him or her to The Point Resource Center: www.ThePointRI.org 401-462-4444 (Voice) or 401-462-4445 (TTY) or a local Medicare Prescription Drug Coverage Forum posted on the HEALTH website.

Additionally, representatives from CMS are available to make presentations about PDP coverage to medical practices, PHOs, IPAs and other physician groups. Please contact Sharon Marable, MD, MPH, at 401-222-5353 for more information.

CONCLUSION

The tagline for the new Medicare Prescription Drug coverage program

is "help is here." Although the new program may overall be a significant health policy intervention for our seniors, this initiative adds another layer of complexity and bureaucracy to the art of medicine. The Medicare Prescription Drug Coverage Program is more than a prescription drug benefit—there also are components of chronic disease management and clinical quality improvement for the provider to keep in mind.

Although Medicare Prescription Drug Coverage is a federal program, we, the medical community, have the opportunity to work together and troubleshoot the local health care challenges and barriers which may come into fruition as a result of this pro-

gram. If we join together, help WILL be here in Rhode Island for the physician, from the power of physician collaboration and unity.

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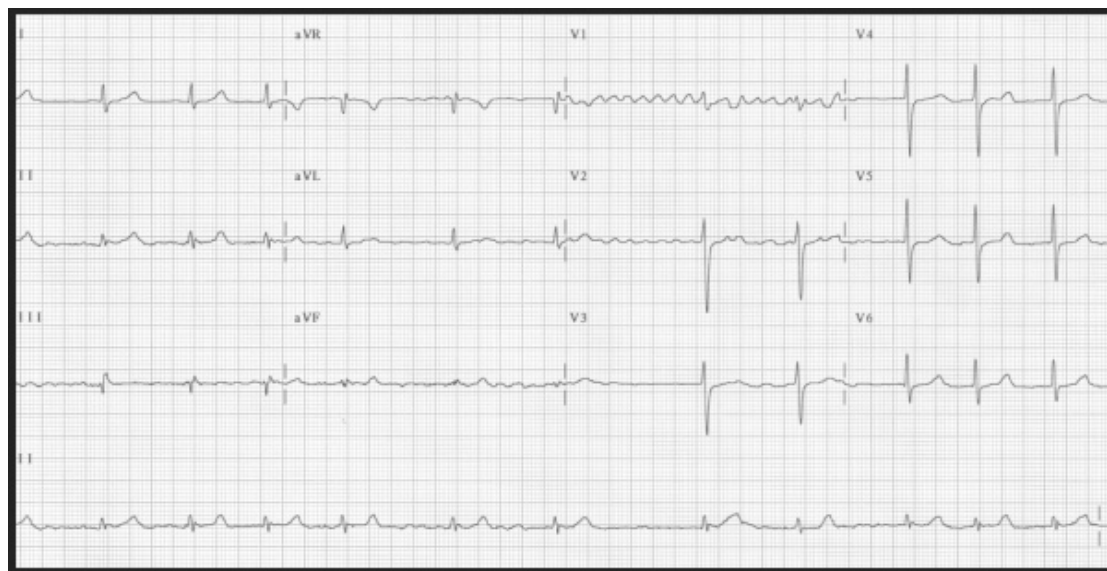
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IMAGES IN MEDICINE

ATRIAL FIBRILLATION

ALFRED E. BUXTON, MD

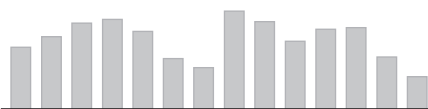


This is an example of atrial fibrillation. Although the fibrillatory activity appears coarse in lead V1, this is not atrial flutter. Atrial fibrillation occurs in approximately 30% of patients after cardiac surgery. In most cases the tendency for fibrillation resolves within one month after surgery. Surgical procedures to cure atrial fibrillation are being explored. These procedures are considered investigational, and are performed only under controlled conditions.

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HEALTH BY NUMBERS

RHODE ISLAND DEPARTMENT OF HEALTH • DAVID GIFFORD, MD, MPH, DIRECTOR OF HEALTH
EDITED BY JAY S. BUECHNER, PHD

TERTIARY CARDIAC CARE SERVICES IN RHODE ISLAND

JAY S. BUECHNER, PHD

The Hanaway Act of 1996 (Rhode Island General Laws 23-17-45) authorized the Director of Health “to establish through regulation quality and volume related standards to be achieved and maintained for specific tertiary health care services ... where peer reviewed medical and health literature establishes significant relationships between desired quality related outcomes and the volume of services provided.” Under this authority, the Director has promulgated regulations covering hospitals’ provisions of the following services:

- Neonatal intensive care units
- Coronary angioplasty programs
- Coronary artery bypass graft (CABG) surgical programs,
- Heart and/or liver transplant programs

For each of these services, the peer-reviewed medical literature supports a minimum utilization volume for facilities above which patient outcomes are significantly better in general than in facilities where service volumes are below the minimum.¹

The regulations cover the services, equipment, and staffing requirements for each tertiary service and set minimum standards for annual utilization and outcomes in order to receive and maintain designation under the regulations. This report presents information on procedure volumes for the tertiary cardiac care services other than heart transplants, which are not performed in any hospital in Rhode Island.

METHODS

Any hospital providing one or more of the tertiary care services covered by regulation is required to maintain certain operational statistics and report them to the Department of Health’s Office of Facilities Regulation annually. For coronary angioplasty and CABG, the statistics are those listed in Table 1. The annual period covered is the hospital fiscal year (October 1 – September 30), and hospitals submit their reports to the Office approximately 6 months after the end of that period. The procedure volume data for this report were taken from copies of the hospitals’ reports received by the Department’s Center for fiscal years 2001-2004 Health Data and Analysis.

RESULTS

As of October 2004, two hospitals met the regulatory requirements for coronary angioplasty and CABG programs.^{2,3} (Landmark Medical Center was designated for both services as of March 2006.) The two hospitals with cardiac programs were Rhode Island Hospital and Miriam Hospital, which provided these services prior to the enactment of the Hanaway Act and were designated when the regulations for these procedures first went into effect.

For coronary angioplasty, existing programs are required to maintain an annual utilization rate of 400 procedures per year. New programs are required to demonstrate the expecta-

tion of achieving and maintaining this level of utilization within two years of opening a coronary angioplasty program. The annual volumes reported by the two hospitals during the period 2001-2004 appear in Figure 1.

Hospitals in Rhode Island that have CABG surgical programs are required to maintain an annual rate of 500 surgical patients per year who require **cardiopulmonary bypass (CPB)** capability, the majority of whom have coronary artery bypass grafts. New programs are required to demonstrate the expectation of achieving and maintaining this level of utilization within three years of opening a coronary artery bypass graft surgical program. The annual volumes reported by the two hospitals during the period 2001-2004 appear in Figure 2.

DISCUSSION

The Hanaway Act supports the limitation of certain tertiary care services to facilities that can meet quality-driven minimum volume requirements. It provides for an orderly expansion of these services to additional facilities as demand increases and specifies a hospital’s response when its volume decreases below the minimum.

During the period 2001-2004, both Rhode Island Hospital and the Miriam Hospital maintained annual procedure volumes for both coronary angioplasty and CABG that exceeded the minimum volume requirements for these procedures. For coronary angioplasty, the reported volumes were substantially above the minimum level of 400, ranging between 968 and 2,428. In addition, between 2001 and 2004, procedure volumes increased in both hospitals, by 17% at Rhode Island Hospital and by 57% at Miriam Hospital.

However, volumes for procedures requiring CPB capability, including CABG, fell in both facilities between 2001 and 2004, by 26% at Rhode Island and by 21% at Miriam. In 2004, volumes at both hospitals were approaching the minimum of 500 procedures, below which a hospital must submit to the Department a plan to

Table 1. Reporting Requirements for Coronary Angioplasty and Coronary Artery Bypass Graft Programs

- Number of coronary angiographies
- Number of coronary angioplasties, by primary operator
- Number of coronary artery bypass graft (CABG) surgeries, by principal surgeon
- Number of emergency CABG surgeries in the same hospital stay following coronary angioplasty
- In-hospital mortality rate for coronary angioplasty patients
- In-hospital mortality rate for CABG surgical patients
- Number of coronary angioplasties by indication for performing the procedure
- Number of CABG operations by indication for performing the surgery
- Other data as specified by the Director of Health

Figure 1: Utilization of Coronary Angioplasty by Hospital, Rhode Island, Fiscal Years 2001-2004

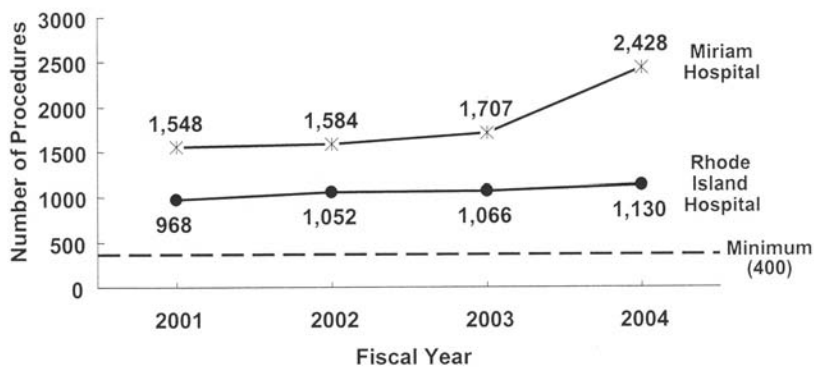
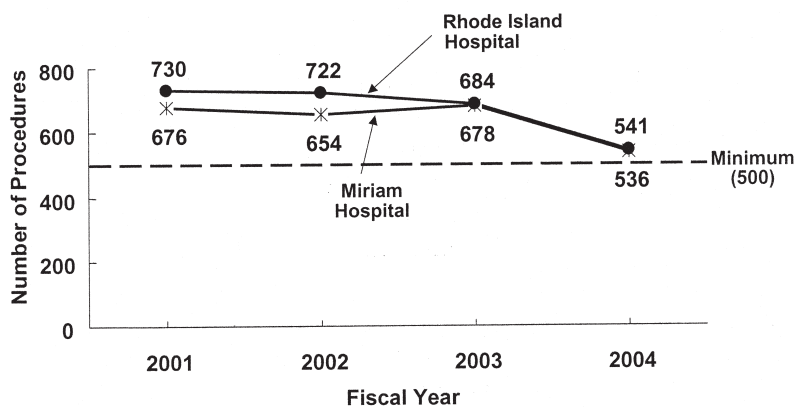


Figure 2: Utilization of Surgical Procedures Requiring Cardiopulmonary Bypass by Hospital, Rhode Island, Fiscal Years 2001-2004



achieve optimal volume standards or refer patients to other appropriate facilities. In the history of the Act, this provision has not been activated for any of the regulated services; however, if the trends in volume for procedures requiring CPB continue, the provision may be triggered within the next few years for one or both of the facilities currently performing these procedures.

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A PHYSICIAN'S LEXICON

A PLETHORA OF QUANTITATIVE PREFIXES

STANLEY M. ARONSON, MD

Classical prefixes denoting relative size or position were increasingly employed as the vocabulary of medical science transcended mere description to become more quantitative. The rush to define size necessarily exploited a range of Greek and Latin prefix-modifiers, many with overlapping meaning, and some with subtle gradations of intent.

Thus, we have *hemi-* [Greek, meaning half; as in words such as hemiplegia and hemisphere], *semi-* [Latin, in words such as semicolon and semiannual] and *demi-* [Latin, from the word *dimedius*, meaning one half and *di-*, a prefix denoting apart or asunder; as in words such as demigod or demimonde.] And thus while *hemi-*, *semi-* and *demi-* seem to be freely interchangeable, custom has dictated that we say hemisphere rather than demisphere and demigod rather than hemigod. The Latin *sesqui-* is a contraction of *semisque* and is usually defined as meaning one-half or more. *Quasi-*, a Latin prefix derived from the phrase, *quam si*, is taken to mean almost as much as, or not quite [as in quasi-scientific.]

The Greek language provides many quantitative prefixes including *macro-* meaning large [as in macrocosm or macroscopic], *micro-* meaning small [as in microbe, microgram and microcephaly], *hyper-* meaning excessive [as in hyperacusis, hyperbole, hyperventilating], *mega-* meaning mighty or abundant [as in megalith and megawatt] and *megalo-* meaning pathologically enlarged [as in megalomania, acromegaly and megalencephaly.]

The Romans, in truth, provided an even greater menu of quantitative prefixes or words. These include *maximus* [meaning the greatest, as in maximum] and *minimus* [the least or the smallest], *magistratus* [meaning masterly as in magistrate or magisterial]. The English word, *minister*, meaning servant of God, is a term designed to emphasize the humility of the position. But words incorporating the root, *magus*, as in magic or Magi, are derived from a Persian word meaning priest.

The Romans offered further quantitative prefixes such as *super-* [as in English words such as sovereign, superb and soprano], *sub-* [as in subversive], *summa-* as in words such as summary, summit. and consummate], *inter-* as in intermediate and *praeter-* meaning beyond [as in preternatural.]

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FIFTY YEARS AGO, JANUARY 1956

James M. Batty, MD; Carrolle Z. Berman, MD; and Orvan Swenson, MD, all of Tufts School of Medicine, contributed "The Management of Children with Abdominal Pain." They reviewed all such cases over a three-year period at the Boston Floating Hospital (4.5% of all admissions).

Raymond McAndrew, MD, and Vartain Papazian, MD, discussed "Islet Cell Adenomas of the Pancreas," at the Friday Conference of the Department of Surgery, Rhode Island Hospital.

Thad A. Kolicki, MD, in "The Role of the General Practitioner in Colon Disease," urged teamwork of the general practitioner, the proctologist, the roentgenologist, and the surgeon.

Raymond H. Trott, MD, discussed 11 of his cases in "Treatment of Colles Fracture without Anesthesia."

TWENTY-FIVE YEARS AGO, JANUARY 1981

Mary Ann Passero, MD, contributed a guest editorial: "Physician Responsibility for Sweat Test Accuracy." From 1973-1980 five patients (ages 4 weeks to 14 months) had presented "with an acute chronic productive cough, steatorrhea, and history of poor weight gain." Community hospital or commercial medical laboratories had interpreted their sweat electrolyte analyses as "normal." The infants were ultimately referred to the cystic fibrosis center at Rhode Island Hospital for evaluation. Dr. Passero cautioned: "Relatively few non-center laboratories perform enough sweat tests to insure technical competence."

Stanley M. Aronson, MD, drew together "Special Papers on Caring"; i.e., "Pastoral Counseling and Dimensional Healing" (Rev. Paul Sanderson, PhD); "Hospice: Family-Centered Care of the Dying" (Robert J. Canny); Interfaith Health Care Ministries" (Rev. Duane Parker, PhD); "The Samaritans" (Carolyn Benedict-Drew).



RHODE ISLAND DEPARTMENT OF HEALTH
DAVID GIFFORD, MD, MPH,
DIRECTOR OF HEALTH

VITAL STATISTICS

EDITED BY ROBERTA A. CHEVOYA, STATE REGISTRAR

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data
from the
Division of Vital Records

Underlying Cause of Death	Reporting Period			
	January 2005	12 Months Ending with January 2005		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	341	2,963	277.0	4,740.0
Malignant Neoplasms	209	2,507	234.4	6,959.0
Cerebrovascular Diseases	42	479	44.8	845.0
Injuries (Accident/Suicide/Homicide)	38	431	40.3	6,883.5
COPD	76	477	44.6	500.0

Vital Events	Reporting Period		
	July 2005	12 Months Ending with July 2005	
	Number	Number	Rates
Live Births	1334	13,342	12.5*
Deaths	771	10,224	9.6*
Infant Deaths	(9)	(93)	7.0#
Neonatal deaths	(9)	(79)	5.9#
Marriages	912	7,786	7.3*
Divorces	292	3,284	3.1*
Induced Terminations	444	5,417	406.0#
Spontaneous Fetal Deaths	76	1,031	77.3#
Under 20 weeks gestation	(62)	(952)	71.4#
20+ weeks gestation	(14)	(79)	5.9#

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

(b) Rates per 100,000 estimated population of 1,069,725

(c) Years of Potential Life Lost (YPLL)

Note: Totals represent vital events which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.

* Rates per 1,000 estimated population

Rates per 1,000 live births

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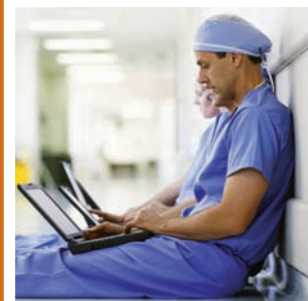
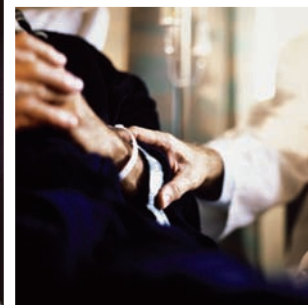
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