The Future of Cardiovascular Biomedicine

The Future of Cardiovascular Surgery

Richard J. Shemin, MD

Cardiac surgery has been a vibrant field since the early pioneering procedures were attempted, became successful, and eventually reproducible. From the successful closure of a patent ductus arteriosus in 1938 and the Blalock-Taussig shunt, discovery and innovation have been the hallmarks of cardiac surgery. Dr. John Gibbon’s first clinical use of the heart lung machine in 1953 opened the door to diverting the circulation and oxygenating the blood, making open heart surgery to repair congenital defects and valvular lesions possible. The development of safe myocardial preservation with solutions to protect the heart opened the surgical world to complex prolonged cardiac procedures and made cardiac transplantation feasible. Routine preservation of myocardial structure and function for periods of several hours has been achieved.

The future holds dramatic advances that will transform the cardiac surgeon, in part, into an interventionalist with new skills in diagnostic and therapeutic approaches to structural heart disease.

Ischemic Heart Disease

The burden of ischemic heart disease in our society challenges the multiple approaches used to treat coronary artery disease. Advances in primary and secondary prevention have finally had an impact; however, current therapy for acute myocardial infarction is primarily culprit vessel percutaneous coronary intervention or occasionally coronary artery bypass surgery. Surgery has been necessary for the mechanical complications of myocardial infarction including mitral regurgitation, ventricular septal defect, or cardiac rupture. However, the future will see the effective use of percutaneous closure devices for postinfarction ventricular septal defect and the use of a variety of devices for acute postinfarction mitral regurgitation.

Treatment of unstable angina, chronic stable angina, or left main disease remains a dynamic field with competing interventional and surgical approaches. Data from randomized clinical trials and larger registries have helped define subgroups and have informed us of some of the best treatment strategies for patient subsets. Professional cardiology and surgical societies have collaboratively developed appropriate-use criteria and practice guidelines. These efforts will continue to evolve and help focus physicians on best practices, reducing practice variation and unnecessary or harmful procedures.

Efforts to explore new ways to combine interventional and less invasive surgical techniques are being instituted and studied. An example, in 3-vessel disease, is the use of percutaneous coronary intervention to the right coronary artery and circumflex vessels and the robotic left internal mammary artery harvest with an off pump beating heart minimal access left internal mammary artery to left anterior descending coronary artery anastomosis. Performing these procedures in a hybrid room allows surgical and interventional procedures to be performed seamlessly.

Valvular Heart Disease

Exciting advances have occurred with the introduction of transcatheter aortic valve replacement (TAVR) clinical trials and subsequent approval of the devices for the treatment of aortic stenosis. The burden of aortic stenosis, a very lethal condition once symptoms develop, is well documented. Many patients are untreated because they are deemed too old, too frail, or have too many comorbidities to undergo conventional or minimally invasive cardiac surgery.

The results from TAVR trials for the inoperable aortic stenosis subset of patients in comparison with medical therapy have been positive and led to the initial US Food and Drug Administration approval of these devices. Further results, from the trials between 2 and 5 years after a TAVR procedure in comparison with conventional surgical aortic valve replacement, have shown equivalence in procedural mortality and short-term survival.

In addition to the frail and elderly patients with multiple comorbidities now having the TAVR option, the future will see these devices used in lower-risk and younger populations. Valve tissue durability will become an important concern as use expands in this way. Future directions in tissue preservation and preservation will focus on enhancing durability: the vision of valve leaflets bioengineered with custom-designed scaffolds seeded with the patient’s own stem cells that will differentiate into autologous leaflet tissue capable of regeneration and remodeling. The result may be a more durable tissue than the current glutaraldehyde-fixed pericardial tissue.

Many of the early TAVR problems have been resolved with improved design both of the valves and of their delivery systems. The ability to perform more of the procedures from a transfemoral approach has resulted from the redesign of the delivery systems. In addition, fabric skirts around the bottom of the valves have helped reduce the incidence of paravalvular leak, which contributes significantly to postoperative morbidity and mortality over time. The risks of periprocedural stroke have been markedly reduced by improved delivery systems that can be shaped and flexed to deliver the valve into the
aortic valve position, minimizing contact with the aortic arch. Future improvements will continue in delivery technologies and other valve designs that will compete with the 2 currently approved US Food and Drug Administration valves.

The development of cerebral protection devices to be used to reduce further neurological events is moving forward. The transapical, transaortic, and subclavian approaches remain options when a femoral access is not possible. A major advance is the ability to perform these procedures with conscious sedation instead of general anesthesia. This approach avoids intubation, transesophageal echocardiography, and an obligate stay in the intensive care unit. The goal is to reduce morbidity, length of hospitalization, and procedural cost.

Real-world large data sets will be analyzed to study practice patterns, determine outcomes, and identify best practices. The use of large registries in the field of cardiac surgery and cardiology has been well established and will continue to be expanded and funded into the future. These data will direct future research, identify knowledge gaps, and establish best practices.

The expansion of transcatheter device implantation techniques for the mitral valve will be the next frontier for device development, delivery systems, and clinical trials. The currently approved MitraClip, which is based on the Alfieri stitch concept, has been approved in the United States for prohibitive-risk surgical patients with mitral valve regurgitation attributable to degenerative disease. Expansion of this technology to other subsets of mitral regurgitation (eg, ischemic mitral regurgitation) and eventually to lower-risk populations will be the next direction for investigation.

Devices for coronary sinus implantation are under development to create an annuloplasty interventionally. There are many technical challenges in this area that will need to be overcome to produce effective devices. The surgical literature supports the combined use of an annuloplasty with the Alfieri edge-to-edge repair to maximize the results and durability of the repair.

Transcatheter mitral valve replacement devices have many design and delivery challenges. These devices are in various stages of development. The mitral valve is a much more difficult valve position and structure for which to develop a replacement device in comparison with the aortic valve position. The access via the left ventricular apex will probably be the most efficient and direct approach used; however, alternative antegrade approaches through the venous system with a transseptal puncture to deliver the device into the left atrium will eventually be developed to reduce the risk of the procedure and avoid a surgical incision. Device positioning, stabilization, and the capture of the anterior leaflet to prevent systolic anterior motion–induced left ventricular outflow tract obstruction and chordal entanglement will all be challenges that need to be overcome in developing these devices and the techniques for their implantation.

Expansion of the transcatheter valves to treat tricuspid and pulmonic valve lesions will continue to evolve. The current use of the Melody valve in the pulmonary position, primarily for congenital pulmonic stenosis, is well established. Tricuspid regurgitation is a serious valvular lesion, and conventional surgery for it bears significant risks. A reliable transcatheter tricuspid valve has great promise.

The use of transcatheter valves for valve-in-valve positioning will become routine in the future. The uses of these valves to treat structural failure of bioprosthetic valves have shown promising results in the aortic and the pulmonic position. There is a need to have a percutaneous approach to treat failed bioprosthetic valves and repairs in the mitral position. Specific knowledge of the geometry of the failed bioprosthesis or annuloplasty band/ring is paramount to determine the size of the percutaneous device.

The option of transcatheter valves used valve-in-valve has expanded the choice of a bioprosthetic valve to a younger age group. The hope is that early bioprosthetic valve deterioration requiring open surgical reoperation can be obviated by the valve-in-valve technique extending the function of the valve without open reoperation. The expected impact will be a reduced need for mechanical valves that require obligate life-long anticoagulation and its attendant morbidity and mortality. There are concept designs for valves that can be placed in the inferior vena cava to reduce the consequences of severe right heart failure’s impact on the development of cardiac cirrhosis and other comorbidities that develop from high venous pressure.

One of the most exciting and positive impact of the transcatheter valve trials in the United States, which has become a new standard in clinical practice, is the development of Heart Teams. Cardiologists (both clinical and interventional) and cardiac surgeons evaluate all high-risk patients as an integrated team in a joint clinic setting and make a single joint recommendation after consideration of the individual needs of the patient. The patient may have to continue medical therapy or be a candidate for a TAVR or surgical aortic valve replacement procedure. This is a very patient-centric approach and eliminates the usual dynamics in clinical decision making that often results from competing technologies and physicians competing with each other to perform a procedure. In addition, the interventional cardiologist and cardiac surgeon are both scrubbed and perform the procedure together, further aligning incentives. The TAVR payment determination by Centers for Medicare & Medicaid Services has resulted in the TAVR procedure having shared payment between surgeons and interventional cardiologists. Thus, the physician stakeholders are aligned in the patient’s best interest both in joint decision making, the joint technical performance of the procedure, and financially, as well. This model has led to improve dynamics and cooperation between the healthcare professionals. This approach has reversed a trend that has been adversarial in the treatment of ischemic heart disease resulting from the competition between percutaneous coronary artery intervention and coronary artery bypass surgery.

### Cardiac Transplantation and Mechanical Circulatory Support

The major advances expected in the arena of cardiac transplantation are continued improvement in control of immunosuppression, reduction of infections, monitoring for rejection without the need for endomyocardial biopsy, and advances in
organ preservation and transport. Currently, with cardioplegic arrest of the donor heart followed by cold storage, the upper limit of reliable myocardial protection to prevent primary graft dysfunction is \( \approx 6 \) hours. Techniques and technologies to harvest the heart and to place the organ in a sterile device that allows coronary perfusion with donor blood perfusing the heart and allowing the heart to beat in an empty state are under investigation. The organ procurement system allows transport of the donor heart in the device. The heart is then reaerist in the recipient’s hospital and transplanted. \(^{13,14}\) Initials trials demonstrate noninferiority to standard cold storage with transport of the donor heart in donor runs <6 hours. New trials are being developed for extended time of cardiac storage. If these trials are successful, a broader range in distance and the time of day the heart can transplanted will be possible. The heart can be metabolically monitored on the storage device, as well, which could prevent the implantation of a damaged organ and reduce the serious problem of primary graft dysfunction.

Mechanical circulatory support has had rapid growth. The devices are becoming more efficient with reductions in size, and they are more likely to be continuous-flow than pulsatile pumps. The US Food and Drug Administration has approved many such devices, both for destination therapy and also for a bridge to transplantation. A total artificial heart used as a bridge to transplantation in both adult (70 mL) and pediatric size (50 mL) are now available. This device requires the removal of the ventricles and has been particularly helpful in cardiac restrictive diseases and chronic postoperative rejection. Nonpulsatile axial flow devices of the future will become smaller, more efficient, and implanted with minimally invasive or percutaneous approaches.

Advances are needed in surface compatibility to reduce the thrombogenicity of these devices leading to device malfunction and thromboembolic ischemic stroke. New more effective anticoagulants with minimal side effects are required. Understanding each person’s individual response to a particular drug will allow improved efficacy and minimize complications. There is an increasing need for implantable devices to support the right ventricle in addition to the left ventricle, because biventricular failure is a major high-risk clinical problem. The current practice of total circulatory support will be challenged by investigations studying whether or not smaller devices are becoming more efficient with reductions in size, and they are more likely to be continuous-flow than pulsatile pumps. The US Food and Drug Administration has approved many such devices, both for destination therapy and also for a bridge to transplantation. A total artificial heart used as a bridge to transplantation in both adult (70 mL) and pediatric size (50 mL) are now available. This device requires the removal of the ventricles and has been particularly helpful in cardiac restrictive diseases and chronic postoperative rejection. Nonpulsatile axial flow devices of the future will become smaller, more efficient, and implanted with minimally invasive or percutaneous approaches.

Advances are needed in surface compatibility to reduce the thrombogenicity of these devices leading to device malfunction and thromboembolic ischemic stroke. New more effective anticoagulants with minimal side effects are required. Understanding each person’s individual response to a particular drug will allow improved efficacy and minimize complications. There is an increasing need for implantable devices to support the right ventricle in addition to the left ventricle, because biventricular failure is a major high-risk clinical problem. The current practice of total circulatory support will be challenged by investigations studying whether or not smaller devices are becoming more efficient with reductions in size, and they are more likely to be continuous-flow than pulsatile pumps. The US Food and Drug Administration has approved many such devices, both for destination therapy and also for a bridge to transplantation. A total artificial heart used as a bridge to transplantation in both adult (70 mL) and pediatric size (50 mL) are now available. This device requires the removal of the ventricles and has been particularly helpful in cardiac restrictive diseases and chronic postoperative rejection. Nonpulsatile axial flow devices of the future will become smaller, more efficient, and implanted with minimally invasive or percutaneous approaches.

Advances are needed in surface compatibility to reduce the thrombogenicity of these devices leading to device malfunction and thromboembolic ischemic stroke. New more effective anticoagulants with minimal side effects are required. Understanding each person’s individual response to a particular drug will allow improved efficacy and minimize complications. There is an increasing need for implantable devices to support the right ventricle in addition to the left ventricle, because biventricular failure is a major high-risk clinical problem. The current practice of total circulatory support will be challenged by investigations studying whether or not smaller devices are becoming more efficient with reductions in size, and they are more likely to be continuous-flow than pulsatile pumps. The US Food and Drug Administration has approved many such devices, both for destination therapy and also for a bridge to transplantation. A total artificial heart used as a bridge to transplantation in both adult (70 mL) and pediatric size (50 mL) are now available. This device requires the removal of the ventricles and has been particularly helpful in cardiac restrictive diseases and chronic postoperative rejection. Nonpulsatile axial flow devices of the future will become smaller, more efficient, and implanted with minimally invasive or percutaneous approaches.

Advances are needed in surface compatibility to reduce the thrombogenicity of these devices leading to device malfunction and thromboembolic ischemic stroke. New more effective anticoagulants with minimal side effects are required. Understanding each person’s individual response to a particular drug will allow improved efficacy and minimize complications. There is an increasing need for implantable devices to support the right ventricle in addition to the left ventricle, because biventricular failure is a major high-risk clinical problem. The current practice of total circulatory support will be challenged by investigations studying whether or not smaller devices are becoming more efficient with reductions in size, and they are more likely to be continuous-flow than pulsatile pumps. The US Food and Drug Administration has approved many such devices, both for destination therapy and also for a bridge to transplantation. A total artificial heart used as a bridge to transplantation in both adult (70 mL) and pediatric size (50 mL) are now available. This device requires the removal of the ventricles and has been particularly helpful in cardiac restrictive diseases and chronic postoperative rejection. Nonpulsatile axial flow devices of the future will become smaller, more efficient, and implanted with minimally invasive or percutaneous approaches.

Advances are needed in surface compatibility to reduce the thrombogenicity of these devices leading to device malfunction and thromboembolic ischemic stroke. New more effective anticoagulants with minimal side effects are required. Understanding each person’s individual response to a particular drug will allow improved efficacy and minimize complications. There is an increasing need for implantable devices to support the right ventricle in addition to the left ventricle, because biventricular failure is a major high-risk clinical problem. The current practice of total circulatory support will be challenged by investigations studying whether or not smaller devices are becoming more efficient with reductions in size, and they are more likely to be continuous-flow than pulsatile pumps. The US Food and Drug Administration has approved many such devices, both for destination therapy and also for a bridge to transplantation. A total artificial heart used as a bridge to transplantation in both adult (70 mL) and pediatric size (50 mL) are now available. This device requires the removal of the ventricles and has been particularly helpful in cardiac restrictive diseases and chronic postoperative rejection. Nonpulsatile axial flow devices of the future will become smaller, more efficient, and implanted with minimally invasive or percutaneous approaches.
circuits. These approaches reduce complications, blood usage, infections, postoperative pain, and wound-healing problems. The recovery and disability time is shortened by weeks.

An important example is a small minimal access intercostal right thoracotomy mitral valve repair with or without the use of the Da Vinci Robot. The small-incision approach to aortic valve replacement is becoming standard. Small-incision minimally invasive direct coronary artery bypass uses the Da Vinci Robot to harvest the left internal mammary artery and then perform the left internal mammary artery to the left anterior descending coronary artery anastomosis. Other less invasive approaches will be enabled when performed in hybrid operating room/catheterization laboratory suites equipped with highly integrated imaging capability. Minimal access valve replacement, minimal access maze procedures, and combined intervention and minimal access surgical procedures hold great promise. Widespread adoption will require trials to prove these concepts and new procedures accomplish the goals of efficacy, durability, and cost-effectiveness.

Conclusion

The future is bright for advances in the treatment of cardiac diseases. The cardiac surgeon is evolving into an interventional cardiac specialist to complement conventional surgical skills. The Heart Team has been a patient-focused advance that allows the expertise of all the relevant cardiovascular specialists to consult and recommend the best evidence-based treatment plan for each patient. Personalized medicine is enhanced by these strategies. Cost pressures will increase and continue to challenge cardiovascular medicine. Therefore, therapies that provide value, extend life, and relieve human suffering are essential.

Disclosures

None.

References


Key Words: arrhythmia, sinus ¬ cardiovascular surgical procedures ¬ heart transplantation ¬ heart value diseases ¬ minimally invasive surgical procedures ¬ myocardial ischemia
The Future of Cardiovascular Surgery
Richard J. Shemin

Circulation. 2016;133:2712-2715
doi: 10.1161/CIRCULATIONAHA.116.023545
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2016 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the
World Wide Web at:
http://circ.ahajournals.org/content/133/25/2712

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published
in Circulation can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial
Office. Once the online version of the published article for which permission is being requested is located,
click Request Permissions in the middle column of the Web page under Services. Further information about
this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation is online at:
http://circ.ahajournals.org//subscriptions/