Recommendations of the National Heart, Lung, and Blood Institute Working Group on Future Direction in Cardiac Surgery

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Abstract—New surgical procedures, imaging modalities, and medical devices have improved therapy for many patients and made treatment possible for others who have had few options in the past. In February 2004, the National Heart, Lung, and Blood Institute’s (NHLBI) Advisory Council proposed that the institute evaluate the status and future directions in cardiac surgery. In response to this recommendation, the NHLBI convened a working group of cardiac surgeons on May 7 and 8, 2004, to assess the state of cardiac surgery research, identify critical gaps in current knowledge, determine areas of opportunity, and obtain specific recommendations for future research activities. The working group discussed surgical revascularization, novel surgical approaches, valvular research directions, biotechnology and cell-based therapy, heart failure, imaging modalities, and barriers to clinical research and presents its recommendations here. (Circulation. 2005;111:3007-3013.)

Key Words: surgery ■ heart diseases ■ research

Although cardiac surgical procedures are still among the most invasive and expensive therapeutic techniques in modern medicine, surgical therapy remains widely used because it provides definitive therapy for those with severe coronary, valvular, or myocardial disease. Myocardial revascularization with CABG provides a mortality benefit in defined populations. Even in this era of widespread use of percutaneous catheter interventions for myocardial revascularization, more than 300,000 patients undergo CABG surgery annually in the United States. An increasing percentage of these patients, currently >50% at most centers, are older (>65 years) and have multiple comorbid conditions related to generalized atherosclerosis. Heart valve prostheses have resulted in improved survival and quality of life for many patients with end-stage heart disease from obstructed or leaking native heart valves. Complex implantable pumps have been shown to provide effective short-term treatment for the failing heart, and long-term mechanical support for severe heart failure (HF) may soon become feasible. Heart transplantation, once considered a risky, experimental procedure, has now been established as usual care. Some of the most exciting advances in the past decade have been in pediatric heart surgery, where surgical researchers have pioneered such lifesaving procedures as definitive repair of the hypoplastic left heart syndrome.

The evolution of cardiac surgery warrants consideration of how to realize the potential of novel therapies and technologies. For example, clinical trials could resolve controversy regarding the relative benefit of procedures that avoid the time-tested use of cardiopulmonary bypass and could reduce uncertainty about methods to protect neurological function during cardiac surgery. New minimally invasive procedures and robotics offer opportunities for comparisons with standard open chest surgery. Use of new technologies, such as pluripotent stem cell or myoblast implants and new imaging modalities, and use of existing technologies in innovative ways, such as circulatory assist devices with adjuncts to promote heart muscle recovery, may be fruitful areas of research. Tissue-engineering principles show promise for advancing the development of heart valves, vascular conduits, and muscle patches, but progress to date has been slow.

The National Heart, Lung, and Blood Institute’s (NHLBI) Working Group on Future Directions in Cardiac Surgery was charged with reviewing current research directions in cardiac surgery and developing 5 high-priority recommendations for future work in the field. The group was urged to consider cost-effective strategies to identify opportunities to partner with industry and create the efficient, multidisciplinary research teams envisioned in the National Institutes of Health’s roadmap.
Surgical Revascularization: Improving Outcomes

CABG surgery is well established, but variation exists in the use, type, frequency, and method of delivery of cardioplegia. Determining best practices for CABG through clinical research might improve outcomes. The recent adoption by some surgeons of CABG on the beating heart, or off-pump CABG (OPCAB), mandates a careful examination of OPCAB versus conventional methods.

Myocardial Preservation

Current methods for myocardial preservation provide satisfactory outcomes for most patients undergoing routine procedures. Although numerous cardioplegic solutions are in use, with many different delivery methods, the optimal procedure has not been determined. For patients at high risk for complications, such as those who present with acute myocardial infarction, in cardiogenic shock, or receiving cardiopulmonary resuscitation, better methods are needed. Large-animal models are an important tool for preclinical testing of new myocardial protection strategies. Although several clinical trials have focused on improving myocardial preservation, trials are needed that focus specifically on high-risk groups.

Neurocognition

Improved methods to prevent neurological complications such as stroke, transient postoperative encephalopathy, and cognitive decline remain a high priority. Developing better neuroprotective techniques will require researchers to identify the precise mechanisms of neurological injury and to test strategies for preventing it. Although several factors, such as embolization of particulate matter into the cerebral circulatory bed, anesthetic drugs, systemic inflammation, and reduced blood flow to the brain, are believed to contribute to neurological complications, the precise influence of such factors in the occurrence of these complications has yet to be established. How the patient’s comorbid conditions and genetic profile contribute to neurological injury is also unknown.

Recent experimental work has focused on potential neuroprotectant agents, including excitotoxic antagonists, preconditioning agents, and antiinflammatory drugs. Additional basic and clinical studies are needed to assess their therapeutic potential. In clinical practice, standardized guidelines for cardiopulmonary bypass operating procedures and for optimal anesthetic techniques could reduce the incidence of neurological complications. Precautions such as the prevention of unintended hyperthermia, optimization of aortic cross-clamping techniques, and avoidance of the introduction of emboli can prevent neurological injury. Consistent, universal implementation of such measures is considered a priority.

At present, progress in research on neurocognition is hindered by varying psychometric and cognitive testing methods and by terminology. Researchers must develop a uniform standard for determining the degree of neurocognitive decline that is clinically significant. Interpretation of the current literature is also hampered by the lack of appropriate control groups in many of the published reports on clinical studies of neurocognition after revascularization surgery.

Off-Pump Coronary Artery Bypass

Although cardiopulmonary bypass may reduce the technical difficulty of performing CABG surgery, it also contributes to the risk of specific complications, such as perfusion-related embolization, hypoperfusion, generalized inflammatory response, and anemia. Consequently, a number of surgeons perform OPCAB, in which cardiopulmonary bypass is avoided, in an effort to avoid perfusion-related complications. Definitive data establishing the superiority of one technique over the other are lacking. Retrospective reviews of large databases such as the Society of Thoracic Surgeons National Adult Cardiac Surgery Database and the Department of Veterans Affairs Continuous Improvement in Cardiac Surgery Program suggest that OPCAB is associated with a decrease in risk-adjusted mortality and morbidity. Smaller prospective, randomized clinical trials comparing OPCAB with pump-based CABG have produced varying results, even when only graft patency is examined. Such conflicting information has led to adoption of OPCAB in a haphazard manner that poorly serves the large patient population with coronary artery disease. Currently, fewer than 25% of coronary revascularizations are performed without cardiopulmonary bypass, and this percentage of OPCAB procedures has not increased over the last 3 years.

A large multicenter, randomized clinical trial comparing OPCAB and CABG is needed to resolve uncertainty regarding their relative benefits. For CABG, it would be important to standardize cardioplegia techniques and the management of cardiopulmonary bypass. For OPCAB, anesthetic management, the use and types of positioning devices, and the surgical techniques, including the sequencing of coronary anastomoses, would need to be considered. It would be necessary to recognize the widely varying levels of experience with OPCAB as well. A trial comparing CABG and OPCAB surgery would also provide an opportunity for studies comparing postoperative neurocognition, renal function, blood usage, and length and cost of hospitalization.

Novel Surgical Approaches

Minimally invasive cardiac surgery (MICS) approaches are currently being explored and developed as a means of minimizing complications. MICS techniques have generally focused on avoiding the use of cardiopulmonary bypass, minimizing incision size, and reducing trauma associated with surgical access. Technological advances in imaging, instrumentation, and robotic devices have paralleled the adoption of MICS and are rapidly being developed and tested. Potential benefits of MICS include reduced wound complications and more rapid wound healing, reduced postoperative respiratory insufficiency, earlier patient mobilization, decreased length of stay and cost, and improved aesthetics. Robotic techniques and enhanced visualization of the surgical field also may result in opportunities for telesurgery and telementoring. Although limiting incision size theoretically may provide such benefits, this will only be true if surgical trauma and tissue injury are reduced by the use of a smaller incision and if the efficacy of the surgical procedure is not compromised by limited access.
Surgical Treatment for Arrhythmias

Despite growing interest in MICS techniques, only a few procedures, such as OPCAB and single valve procedures, are evolved sufficiently for testing in a randomized clinical trial. One notable exception is the recent development of the surgical treatment for atrial fibrillation, for which percutaneous interventions have not fulfilled earlier expectations. There may be significant opportunities to use recent improvements in understanding of the electrophysiology of atrial fibrillation to develop new MICS methods with commercially available devices, such as bipolar ablation clamps, which are less demanding than the traditional cut-and-sew Cox Maze procedure. Although these new devices and techniques for tissue ablation require objective data on what the minimum lesion set is and what the results are in 6 months and 1 year in permanently reducing atrial fibrillation, a randomized clinical trial comparing minimally invasive surgical treatment of atrial fibrillation with catheter-based ablation approaches would be feasible, and such a trial might rapidly lead to a widely available surgical cure.

MICS in the Pediatric Patient

New imaging, instrumentation, and robotics technology are finding applications in pediatric MICS. For most congenital cardiac defects, the precise definition of anatomic and hemodynamic status is a prerequisite for the development of MICS approaches. Advances in imaging may provide an anatomic roadmap that can be used for image-guided surgical repair of such intracardiac lesions as atrial and ventricular septal defects.

As new MICS techniques emerge, innovative educational technology will play a role in training the next generation of surgeons to perform these techniques. Established cardiac surgeons also will require training and mentoring in new techniques that have been developed after the completion of their formal training. Novel surgery training methods with mechanical models, simulators, telementoring, and a virtual curriculum are being developed with computer-enhanced technology. As the number and complexity of cardiac surgical procedures increases and the time available to train residents and fellows decreases, technology-aided alternatives and adjuncts to the traditional apprenticeship system of surgical education will become increasingly important.

Valvular Heart Disease Research Directions

The recent increase in the number of people with HF has increased interest in the repair of ischemic mitral regurgitation associated with HF. In the pediatric population, new technologies are providing tools for the repair of congenital atrioventricular valve defects. In addition, there is continued interest in the development of improved prosthetic valves for both children and adults.

Ischemic Mitral Regurgitation

Ischemic mitral regurgitation (IMR) affects 1.2 to 2.1 million patients in the United States. More than 400 000 in this group have moderate to severe mitral regurgitation. This is expected to increase as the population ages and more patients survive acute myocardial infarction. Because of the long experience and success in treating mitral regurgitation of nonischemic origin, it is widely believed that restoration of normal valve geometry in patients with IMR will lead to more normal valve and ventricular function. Clinical studies have attempted to determine whether valve repair is preferable to replacement in patients with IMR; however, thus far, clinical studies have not provided strong evidence that surgical treatment (repair or replacement) improves long-term outcomes in HF patients with IMR. Recent laboratory experiments have suggested that irreversible changes in the basic biology of the myocardium occur during postinfarction remodeling that cannot be reversed (or prevented) by eliminating IMR. Clinical studies need to be performed to determine whether and under what circumstances repair of IMR in HF patients is efficacious. In addition, greater emphasis should be placed on understanding the biomechanical, cellular, and molecular changes that occur in the myocardium during ventricular remodeling as symptomatic HF evolves.

New Technologies in Valve Replacement

The need for biocompatible prosthetic heart valves is particularly pressing in the pediatric population. Approaches including tissue engineering of valves with autologous cells are currently being investigated for the possible development of valve prostheses. Obstacles to development include a lack of biomaterials with characteristics that promote appropriate cell growth and differentiation and a need to identify the best progenitor cells for use in devices. Furthermore, genetic engineering of these progenitor cells could prove very useful for enhancing their proliferation, facilitating thromboresistance, and reducing inflammatory activity. Preliminary animal model data of implanted tissue-engineered valves have shown promise, but much additional research will be required before this is a real alternative to commercially available prosthetic valves.

Another significant barrier to the development of newer prosthetic valves is the paucity of business interest and funding. Prosthetic valves take a relatively long time to develop, and the risk of ultimate failure is high. Although a few university-based academic groups are working in this area, most researchers lack access to both funding and the technology required for the design of implantable human prosthetic valves. The establishment of design cores in academic centers or government agencies devoted to the production of device prototypes would facilitate the production of novel prosthetic valves and other devices for the treatment of cardiovascular disease. Development could be further encouraged by enabling the testing of new design models in preclinical and phase I trials within a cardiac surgery clinical trials network. Once academic researchers have the tools necessary to move prototypes into later stages of development, their ability to attract industry funding can be expected to increase.

Biotechnology and Cell-Based Therapy

Basic science advances are now converging with clinical research in bringing cell-based and molecular-level treatments for cardiovascular disease into clinical practice. Therapeutic angiogenesis, for example, uses angiogenic factors...
delivered as proteins or via gene therapy to induce cardiac neovascularization. This revascularization strategy is being investigated as a possible treatment for the 10% to 12% of patients with severe coronary artery disease who are not candidates for standard revascularization techniques and for use as an adjunct to conventional surgical procedures. A second technique, cellular cardiomyoplasty, involves implanting precursor muscle cells into areas of myocardial infarction to “repopulate” the myocardial scar tissue with viable myocytes. Translation of these approaches to the clinic has proved challenging.

**Therapeutic Angiogenesis**

Several recent studies have demonstrated the therapeutic usefulness of exogenous growth factors, such as vascular endothelial growth factor and fibroblast growth factor-2, for inducing improvements in myocardial perfusion in large-animal models of chronic myocardial ischemia. Gene therapy studies using adenovirus-mediated transfer of vascular endothelial growth factor cDNA suggest that angiogenic therapy might be useful for treating ventricular dysfunction and for preventing progression of coronary artery disease; however, thus far, clinical trials have failed to demonstrate that therapeutic angiogenesis is as effective in patients. Consequently, a number of studies have focused on understanding why a robust response to angiogenic therapy is observed in animal models but not in clinical trials. Recently, it has been suggested that the failure to see an effect of vascular endothelial growth factor and fibroblast growth factor-2 in patients is related to a deficiency in the stimulated release of nitric oxide. Production of nitric oxide and other factors is significantly altered as a result of disease states such as coronary artery disease, hypercholesterolemia, and other conditions characterized by abnormal endothelial function and increased vascular oxidative stress. The presence of endothelial dysfunction may play a crucial inhibitory role in the response to exogenous angiogenic agents. Adjuvant therapy with agents such as L-arginine or inhibitors of oxidative stress may increase effectiveness of protein growth factor or gene therapy and might play a role in making therapeutic angiogenesis a reality in clinical practice. New imaging technologies will be required to assess the efficacy of angiogenic therapy, and ideally, minimally invasive techniques will be developed to reduce the risks associated with growth factor or gene administration.

**Cell Transplantation**

Results from phase I clinical trials in Europe have demonstrated the feasibility and safety of cellular cardiomyoplasty; however, more studies investigating the basic biology underlying cell transplantation are needed. Currently, a variety of different cell types, including human embryonic stem cells, fetal cardiac muscle cells, skeletal muscle myoblasts, and peripheral and bone marrow stem cells, are being considered as possible donor cells. Ideally, transplanted cells would mimic the lost myocytes morphologically and functionally, with the ability to contract and to establish electrical connectivity with the native myocardial cells.

As with therapeutic angiogenesis, much work is needed to optimize cell transplant techniques. Determining the appropriate cell dose and developing procedures to prevent cell loss, preserve viability, and improve targeted migration to dysfunctional myocardium will be crucially important for success. The use of angiogenic or antiapoptotic factors for pretreatment of the infarcted myocardium is also being investigated as a strategy to enhance survival of the transplanted cells.

**Heart Failure**

The public health implications of HF and the poor long-term survival for affected individuals has fueled interest in finding new therapies to improve survival and quality of life in end-stage HF patients.

**Mechanical Circulatory Assist**

In recent years, productive partnerships between industry and the academic research community have produced steady incremental progress in the development of cardiac assist devices for the management of postcardiotomy shock and bridging to transplantation. The Randomized Evaluation of Mechanical Assistance for Treatment of Congestive Heart Failure (REMATCH) trial showed that long-term left ventricular assist device (LVAD) use prolongs and enhances life over a 2-year period in end-stage HF patients. The trial demonstrated a 48% reduction in the risk of death in the device group compared with patients receiving optimal medical management. The 2-year survival rate of device recipients in the trial has increased from 0% in a preliminary exploratory device trial (PREMATCH) to 23% when first reported, and to 29% at present. No such improvement was seen in medically managed patients. Recently, the HeartMate LVAD used in the trial was approved by the Food and Drug Administration. Within the next year, ~60 centers are expected to begin LVAD destination therapy programs.

Although REMATCH documented a clinically meaningful survival and quality-of-life benefit for patients with implanted LVADs, device implantation was associated with a high frequency of adverse events. Bleeding complications often occur as a result of necessary anticoagulant therapy administered to patients with LVADs. New anticoagulants show promise for preventing the blood clotting that occurs with device implantation without the bleeding associated with coumadin use. In addition, a number of new LVAD designs to reduce infection and device failure will soon be ready for clinical testing. As LVAD technology evolves, additional randomized clinical trials of LVADs for treatment of patients with acute cardiogenic shock and for less severe chronic HF could be undertaken. In the future, “weanable VADs,” support devices that can bridge a patient from cardiogenic shock to recovery, may be feasible.

**Surgical Ventricular Restoration**

Surgical therapies, including CABG for patients with extensive coronary artery disease associated with impaired cardiac function and surgical ventricular restoration (SVR) procedures to reconstruct the dilated left ventricle to restore a more normal ventricular size and shape, are used to treat patients with congestive HF. Few studies have addressed whether optimal surgical interventions provide benefits over optimal medical therapy in patients with coronary artery disease and...
congestive HF. The Surgical Treatment for Ischemic Heart Failure (STICH) trial is investigating whether coronary revascularization is more beneficial than optimal medical management for treatment of such patients and whether benefits provided by revascularization can be enhanced by SVR in patients with significantly dilated ventricles and areas of asynergy that involve the anterior left ventricle. Additional questions related to the effectiveness of SVR procedures remain unanswered.

It is not currently clear how well one can predict viable transition zones preoperatively, whether one can accurately predict the postvascularization function of akinetic segments, or whether the functional improvement in muscle segments remote from the infarct results in a functional or clinical benefit. Research in large-animal models can help address such critical issues related to SVR. Whether imaging technology can be integrated with computer simulation to model patient-specific SVR surgical procedures that result in improved outcomes remains to be explored.

Imaging Modalities for Cardiac Surgery
Evolving cardiac imaging technologies are expected to result in earlier and more accurate diagnosis of heart disease, improve preoperative planning for surgical procedures, facilitate the development of minimally invasive image-guided surgery, and allow for more informative and less-invasive postoperative evaluation of surgical interventions. The revolution in computer-enhanced cardiac and vascular imaging has been particularly important in the development of real-time imaging capabilities for image-guided surgery. In the future, computer-enhanced imaging techniques should allow surgeons to simulate surgical procedures and help assess the relative efficacy of alternative surgical approaches.

Diagnosis
The development of new tools to detect disease at earlier stages of disease evolution could help to prevent disease progression. Refined imaging modalities including MRI\textsuperscript{16,17} and computed tomography (CT)\textsuperscript{18} may be able to detect obstructive coronary artery disease earlier than do traditional tests such as stress echocardiography, stress ECG, and coronary angiography.

Preoperative Surgical Planning
New imaging technologies are allowing surgeons to obtain detailed 3D views of a patient’s heart before surgery. As the quality of image acquisition improves, it may be possible for surgeons to identify and plan for potential technical challenges before surgery and to map out procedures in extensive detail, including the site and size of the surgical incisions. Some of the current pioneering work on imaging for preoperative planning is being studied in pediatric cardiac surgery. 3D echocardiography is being used to plan the repair of atrial or ventricular septal defects. MRI and CT imaging allow surgeons to determine the precise size and shape of the patch that will be needed to correct a defect.\textsuperscript{19}

Researchers are intensely interested in obtaining magnetic resonance and CT tools to measure hemodynamic parameters such as volume, flow, mass, and motion. Quantification of hemodynamic load on vessels and myocardium could be used to increase understanding of disease progression in congenital heart defects and to help clinicians make decisions about treatments. The use of MRI and CT for surgical planning of a number of procedures such as valve replacement, CABG, heart transplantation, and the SVR procedure are currently being investigated.

Image-Guided Interventions
The ability to image inside the heart and blood vessels in real time with imaging techniques (eg, ultrasound and MRI) could lead to real-time evaluation of surgical interventions. The major barriers to the use of ultrasound for image-guided surgery are lack of resolution and the difficulty with instrument-induced artifact. MRI images are of higher resolution and allow precise assessment of myocardial function, perfusion, viability, and morphology. The availability of MRI, however, is limited by a need for instrumentation that is not yet widely available and by a scarcity of surgeons, technologists, and support personnel trained to perform and interpret MRI scans.

Research Directions for Cardiac Imaging
The goals of current imaging research are to continue to improve image resolution, to establish and refine techniques for quantitative imaging, to integrate imaging and instrumentation to allow for the development of image-guided and eventually robotic or remote surgery, and to develop other novel applications for imaging in research, training, and clinical practice. Image registration combines imaging modalities to obtain more information than would be possible with a single technique. Image registration allows combined CT and PET image fusion, which can provide both functional and anatomic data.

New applications for imaging are being used in clinical research. For example, MRI and CT can be used to monitor and evaluate novel therapeutic approaches such as gene therapy, stem cell implantation, and laser revascularization. To encourage the use of new imaging modalities, efforts should be made to incorporate these techniques into clinical trials.

Barriers to Clinical Research
Clinical research in cardiac surgery has tremendous potential to benefit patients and to improve public health. However, if this potential is to be realized, researchers must work actively to overcome several barriers that impede clinical trials of cardiac surgical procedures. Three of the most common challenges are low enrollment of study participants, difficulty in randomizing patients, and crossover from the assigned arm of a clinical trial to another arm of the trial.

Low enrollment often results because patients are reluctant to participate in trials that require invasive treatments when medical management is an alternative option. In other cases, patients refuse to be enrolled or randomized on the basis of their preference for an innovative procedure that has been marketed aggressively, even when there is substantial uncertainty about its efficacy. Bias on the part of individual surgeons and cardiologists toward particular procedures can also impede randomization. Crossover from one arm of a
surgical trial to another can prevent a trial from producing meaningful results by undermining statistical power.

To overcome these barriers, the surgical community must first confront its own biases and consider the data available on different procedures. Surgeons and cardiologists often express the belief that a particular procedure is the most efficacious even when its relative merits remain untested. Recent surprising findings of large clinical trials that contradict the best observational evidence, such as hormone replacement therapy for postmenopausal cardiovascular event prophylaxis, emphasize the importance of randomized trials. After careful review of the scientific literature, the community must reach equipoise, a state in which a significant group of experts believes in each arm of the trial such that neither intervention could be considered substandard care.

All of the barriers to clinical research are penetrable with sustained and sophisticated appeals to the physician community’s scientific and moral ideals. The patient’s well-being is the medical community’s deep-seated goal. Attempting to resolve diagnostic and therapeutic uncertainties by pursuing the best possible scientific methodologies can empower and invigorate both physician and patient. In public education efforts, researchers must emphasize that the central goals of clinical research are both to enhance patient safety and to identify more effective therapies. On the level of direct public and patient interaction, the physician and surgeon must devote the time required to effectively communicate the rationale for and goals of any clinical study. This task is increasingly important for interventional trials that involve significant and disparate early risks. Reinforcing the importance of clinical research to public health and medical advances must continue to be a high priority.

Recommendations

Cardiovascular Surgery Clinical Network

The Working Group recommended the formation of a Cardiovascular Surgery Clinical Network for relatively small, short-term, clinical studies. The Working Group indicated that the network would be an important step in developing a culture for clinical trial evaluation within the field of cardiac surgery that would, over time, increase in productivity and improve prospects for larger trials. They envisioned a network that would include cardiologists and surgeons so that both groups would have ownership in and responsibility for trials that bridged both specialties. The Working Group gave the following examples of the types of trials that would be appropriate for inclusion in the network: (1) a randomized clinical trial comparing minimally invasive surgery with catheter-based ablation approaches for the cure of chronic atrial fibrillation; (2) clinical testing of new valve repair techniques; (3) clinical testing in adults with congenital heart disease of surgery to treat atrial fibrillation; (4) a randomized clinical trial to investigate the efficacy of repair for mild to moderate mitral regurgitation in patients undergoing clinically indicated CABG; (5) an evaluation of the efficacy of CABG with adjunctive LVAD for treating acute myocardial infarction complicated by shock; (6) clinical trials, including organized human dosing studies, to determine the benefit of using cell-based or gene-based therapy as an adjunct to LVADs; and (7) trials of new applications for computer-enhanced imaging, instrumentation, and robotics.

Comparison of On-Pump and Off-Pump CABG

Whether OPCAB results in lower mortality rates or fewer complications than conventional CABG is an important question with major public health implications. The Working Group recommended support for a large, multicenter, randomized clinical trial to compare the procedures and the effect of CABG on neurocognition, renal failure, infection, and blood transfusion requirements, as well as to explore other questions.

Technology Development

The Working Group recommended support for the development of computer-enhanced imaging and instrumentation, robotics, next-generation LVADs, and prosthetics, with a focus on valves, conduits, vessels, and pacers for the pediatric population. The Working Group also identified this as a possible area for collaboration with industry partners. They suggested including these technologies in trials within a Cardiovascular Clinical Surgery Network. They also suggested the establishment of design cores to allow academic researchers to develop device prototypes and encouraged support for basic research on biomaterials for use in prosthetics. Finally, they noted that advances in imaging, instrumentation, and robotics are playing an integral part in the development of novel ex vivo training methodologies.

Large-Animal Models

The Working Group recommended that special emphasis be placed on continued support for the use of large-animal models in cardiac surgery research. The Working Group discussed several studies, including studies related to myocardial preservation and cellular cardiomyoplasty, that relied on the use of large-animal models. They noted that large-animal models play an essential role in the translation of results from basic studies into clinical trials. The difficulty researchers face in obtaining funding for research using large-animal models was identified as a major barrier to research.

New Technologies in Surgical Planning

The Working Group recommended the use of new computerized-imaging technologies and device development to assist cardiac surgeons in the quantification of the hemodynamic load on vessels and myocardium, assess acute and chronic response to cardiac defects, and develop an anatomic roadmap for surgical repair of complex lesions. Although these technological advances have been developed primarily in the realm of pediatric cardiovascular surgery, with its wide variety of fairly unique congenital anatomic variants, the expanded use of computer-assisted imaging can be moved forward to the surgical planning of adult cases, such as mitral valve repair. Such advances will also help meet the expanded need for training of both experienced surgeons and surgical residents in an era of rapid procedural changes.

Appendix

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References


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