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Is the Future of Cardiac Surgery in the Hands of the Interventional Cardiologist?

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INTRODUCTION

Continued advances in the field of interventional cardiology and the recent emergence of new catheter-based technologies (CBTs) for treating heart disease have led cardiac surgeons to question the future of their specialty. Although many of the new percutaneous techniques may ultimately prove effective, it is important to evaluate their potential impact in relation to the rapidly changing specialty of modern cardiac surgery.

BACKGROUND

Percutaneous technology is not the first competing technology to threaten thoracic surgery with obsolescence. Thoracic surgery emerged in the 1920s as a specialty dedicated to the treatment of pulmonary tuberculosis. Surgical therapies included crushing thoracoplasties and intrapleural plombage, procedures that are now virtually forgotten. With the discovery of streptomycin and other effective anti-tubercular drugs in the early 1940s, the future of thoracic surgery seemed bleak. From the experience gained with surgery for tuberculosis, however, it became evident that portions of the lung could be safely resected. The first successful pneumonectomy for cancer, by Dr. Evarts Graham, insured thoracic surgery's future for decades to come.

Valvular heart surgery has seen a similar revolution. Initial attempts at adult cardiac surgery were primarily focused on restoring function to the stenotic mitral valve. With the progressive eradication of rheumatic heart disease, mitral stenosis has become increasingly uncommon in many parts of the world. Nevertheless, advances that included the development of cardiopulmonary bypass (CPB), myocardial protection, and valvular prostheses allowed valve surgery to flourish. Furthermore, as tools and techniques have continued to evolve, surgeons have been able to perform valve procedures on progressively older and sicker patients.

Direct coronary artery bypass grafting (CABG) was introduced in the early 1960s. With subsequent refinements of the heart-lung machine and the development of cardioplegia, cardiac surgery expanded dramatically, with a logarithmic increase in the number of procedures performed and rapid dissemination around the globe. CABG surgery experienced two decades of growth, as there were no procedural alternatives for the treatment of coronary artery disease. However, percutaneous transluminal coronary angioplasty (PTCA) was introduced in 1979. Since then, interventional cardiologists have experienced a boom of their own, with rapid development and refinement of tools and techniques for the percutaneous treatment of atherosclerotic coronary artery disease (CAD). These innovations have dramatically reduced the number of patients referred for CABG. With promising new CBTs on the horizon, one cannot help but wonder if the CABG procedure will endure.

Cardiac surgery is being challenged on other fronts as well. Innovative new CBTs for treating aortic and mitral valve disease, atrial fibrillation, and even congestive heart failure (CHF) may further erode the once large base of cardiac surgical patients. These developments may lead one to ask, "Is the future of cardiac surgery in the hands of the interventional cardiologist?"

Although attempting to predict the future may be unwise (especially in print), we can perform guarded extrapolation. To do that, we must take stock of the present as well as examine the exciting new technologies on the cardiac surgical horizon.

DISCUSSION

Aortic and Mitral Valve Replacement

The results of surgery for valvular heart disease have steadily improved. Operative mortality and morbidity for isolated aortic valve replacement (AVR) is in the 1-3% range despite the fact that patient age has increased over the past three decades. Furthermore, as a consequence of design and manufacturing advances, prosthetic valves are reliable and durable. Bioprostheses last 12-15 years, and mechanical prostheses last indefinitely. Current valve designs have a low incidence of thromboembolic complications. Additionally, with the introduction of the international normalized ratio for monitoring coumadin therapy, the risk of anticoagulation has never been lower. Ongoing work in the field of bioprosthetic and mechanical valve design, as well as the recent advent of stentless tissue valves, may continue to improve the results of AVR.

Nevertheless, safe and reliable AVR performed by way of a catheter without cardiopulmonary bypass or surgical exposure would represent a major advance. The surgical stress of conven-

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tional open AVR, even through a limited sternotomy, is considerable. Even the healthiest patients require weeks to return to baseline function and energy reserve. Now that octogenarians, and even nonagenarians, are routinely referred for AVR, surgical stress and postoperative rehabilitation have become even more pressing issues. However, the challenges inherent in a catheter-based system for AVR remain considerable.

The first CBT for aortic valve disease to find clinical application was balloon aortic valvuloplasty (BAV). Although beneficial in some patients, success was short-lived. The concept of "removing a few straws from the camel's back" by transiently increasing the valve area a few tenths of a square centimeter has occasionally been useful in improving hemodynamic stability in anticipation of AVR, and in determining in high-risk patients whether AVR will be of benefit. However, many patients with concomitant aortic insufficiency or extensive calcific involvement of the leaflets are not candidates for BAV. Accordingly, the utility of BAV has been limited.

More recently, a CBT intended to decalcify valves in the hope of restoring normal function has been introduced. Although this may prove effective in the early stages of aortic stenosis and in slowing progression, it is difficult to imagine any tool restoring function to the majority of the stenotic valves on which cardiac surgeons operate. Perhaps if used judiciously in appropriately selected patients, this technology may slow the progression of aortic valve disease.

Percutaneous deployment of a bioprosthetic or polymer valve-in-a-stent across the native aortic valve is also being investigated. This approach is appealing from several perspectives, but may prove clinically challenging. Over the last four decades, valve prostheses have come and gone by the dozens, leaving only a handful of contenders in the mechanical and bioprosthetic realms. A prosthetic valve must open and close approximately forty million times each year, last at least a decade, and pose an acceptably low risk for thromboembolism. Small design changes have resulted in significant improvements in performance in these areas and have been the major cause of abandonment of inferior designs. Although advances in material sciences and computer modeling have refined the field of valve design, adding the design criteria of collapsibility so that the prosthesis can be introduced through a peripheral artery may prove a prohibitive challenge. The avoidance of sternotomy and CPB, however, is attractive enough that some degree of compromise in prosthesis performance may be acceptable for high-risk patients. The ultimate utility of this CBT will depend on a balance of these factors. Due to the significant regulatory hurdles associated with even subtle variations in prosthetic design, the future of open AVR does not seem to be in immediate peril.

Similarly, several innovative CBTs are being developed for the treatment of mitral valve disease. Balloon mitral valvuloplasty (BMV) for mitral stenosis has fared somewhat better than BAV. However, mitral stenosis is seen with decreasing frequency in most parts of the world. Therefore, it is unlikely that BMV will have a major impact on the number of patients undergoing surgical MVR.

CBTs that address mitral regurgitation (MR) could, however, have an impact. One approach has been to perform an "Alfieri-like" repair (fixating the two coapting surfaces of both leaflets at one point) by way of a catheter. This approach also presents some daunting challenges. Performing the fixation surgically under direct vision in the arrested heart can be challenging enough. Although it is possible that 3-D echocardiography, computer-enhanced cardioscopy, or other imaging modalities may make the procedure easier to perform on a full, beating heart, this technique will have to be demonstrated reproducibly. In addition, more information is needed concerning the durability of this type of repair. Even if the results don't compare favorably with open mitral valve procedures, the benefits of avoiding or postponing surgical MVR and CPB may make the approach attractive for some high-risk patients.

A number of other approaches are being investigated for percutaneous intervention on the regurgitant mitral valve. Like the percutaneous Alfieri stitch, their ultimate utility will depend on ease of use as well as effectiveness and durability. It is possible that these new approaches will be used primarily in the millions of patients worldwide with CHF and significant MR. Patients with New York Heart Association Class IV CHF and MR have a 50% mortality rate at one year from diagnosis, significantly worse than Class IV patients without MR. For most of these patients, the operative risk of MVR is prohibitive. As such, these promising new percutaneous technologies may have a significant impact in this poorly served population but may have little impact on the number of patients who ultimately require mitral surgery.

Coronary Artery Bypass Grafting (CABG)

The most significant threat to the future of cardiac surgery comes from innovative CBTs directed at the treatment of coronary artery disease. Gruentzig reported the first PTCA in 1979. Since then, numerous CBTs have been introduced, including coronary stents, rotational atherectomy, directional atherectomy, LASER-assisted PTCA, direct myocardial revascularization (DMR), intracoronary brachytherapy, biologically active coated stents, and most recently, percutaneous in-situ coronary venous arterialization (PICVA) and percutaneous in-situ coronary artery bypass (PICAB). The ultimate success of each of these will depend to some degree on how they compare over time with what many consider to be the "gold standard" of coronary revascularization: the left internal mammary artery (LIMA) to left anterior descending (LAD) bypass.

It is generally accepted that LIMA-to-LAD grafts are a durable and effective treatment for CAD. It is well recognized that 95% of these grafts are widely patent 10 years after their construction, and that their successful construction confers a survival benefit on the patient. No other therapy, catheter-based or otherwise, has ever been held to this standard. There are, however, many aspects of CABG surgery that make it unattractive. It is these very aspects that have provided the motivation for CBT innovation. These drawbacks include the trauma of surgical access ("cracking the chest"), the surgical trauma required for conduit harvest, the systemic inflammatory response associated with cardiopulmonary bypass, the threat of postoperative neurocognitive dysfunction, and vein graft attrition. Fortunately, there are a

number of new technologies that address these issues and have the potential to decrease the invasiveness of CABG.

Before considering these newer technologies however, it is useful to compare results of CABG and multi-vessel catheter-based intervention using currently available technology. Two studies presented at the 2001 American College of Cardiology meeting in Orlando, Florida undertook this task. The MASS II trial (Medicine, Angioplasty, or Surgery Study) randomized 611 patients to receive either medical therapy, multi-vessel PTCA, or CABG. Seventy percent of patients in the PTCA group received at least one stent. At one-year follow-up, 8% of the medical group and 14% of the PTCA group required additional revascularization, compared with 0% of the CABG patients. Furthermore, 13% of medically treated patients and 25% of PTCA patients experienced recurrent angina, as compared to only 6% of CABG patients. The SoS (Stent or Surgery) trial randomized almost 1000 patients at 53 centers throughout Europe and Canada to receive either multi-vessel stent or CABG. At a median follow-up of two years, 13% of stented patients had to return for additional revascularization, as compared to 4.8% of CABG patients. Furthermore, multi-vessel stenting was associated with 4.1% mortality while the CABG group experienced only 1.2 % mortality.

Interventional cardiologists are quick to point out that stent technology is rapidly changing and that these results do not represent the current state of the art. Biologically active coated stents may improve results significantly. Although impressively low rates of in-stent restenosis have been reported in recent series of patients treated with Rabamycin-coated stents and chronic animal studies have demonstrated minimal intimal hyperplasia, further investigation is needed. Similarly, the role of intracoronary brachytherapy as a primary therapy, or its use in the management of in-stent restenosis, has yet to be defined.

Despite these advances, CBTs in general have not been well suited for patients with large atherosclerotic burden. Patients with diffuse disease, especially those with small vessels, experience a high incidence of restenosis. Patients with left main lesions are also not well suited for stents because, although they are often technically easy to treat, they tolerate restenosis poorly. New stent technology may have a favorable impact on these challenging groups, but this has yet to be demonstrated.

Another group poorly served by current CBTs is comprised of patients with chronic total occlusions (CTOs). Percutaneous in-situ coronary venous arterialization (PICVA) and percutaneous in-situ coronary artery bypass (PICAB) have recently emerged as promising new approaches that allow myocardium distal to CTOs to be revascularized. In PICAB, the neighboring coronary vein is accessed by transmural penetration of the coronary artery proximal to the CTO. The coronary artery distal to the CTO is then accessed from the vein in a similar fashion, using intravascular ultrasound for guidance. A covered stent can then be passed over the wire to create an in-situ coronary-to-coronary graft circumnavigating the CTO. In situations where the coronary artery distal to the CTO is unsuitable for PICAB due to diffuse disease, PICVA may prove beneficial. In a PICVA procedure, the artery-to-vein fistula proximal to the CTO is stented open, resulting in arterialization of the venous bed that drains the ischemic territory. The vein is isolated from the rest of the coronary venous system with a self-expanding blocker to prevent significant left-to-right shunting. These investigative techniques are extremely innovative and offer great promise. Safety and reproducibility have yet to be demonstrated clinically, however, and little is known about the long-term effects of venous arterialization. Although the continued evolution of PICAB, PICVA, and other CBTs may provide additional options for an ever-expanding group of patients, simultaneous cardiac surgical innovations may decrease the incentive for avoiding surgical revascularization.

As alluded to earlier, several aspects of standard CABG make surgery less attractive than catheter-based treatment. Examples include the systemic inflammatory response associated with cardiopulmonary bypass, the threat of postoperative neurocognitive dysfunction, the high incidence of vein graft attrition, the surgical trauma required for conduit harvest, and the trauma of surgical access to the heart. New technologies are being introduced to address each of these issues, however. These advances may have a significant impact on the desirability and utilization of CABG.

Off-pump CABG

There has been a resurgent of interest in off-pump CABG (OPCAB) over the past several years due in part to increased awareness of the potentially harmful effects of cardiopulmonary bypass (CPB). During this period, the development and dissemination of new tools and techniques have made the operation safe and its results reproducible in a broad subset of patients. Although the advantages of avoiding CPB may be subtle for many patients, it is clear that for some patients such avoidance is beneficial.

One suggested advantage of avoiding CPB is the anticipated reduction of post-CABG neurologic injury. It has been demonstrated by careful neurocognitive testing that 30-50% of patients experience detrimental changes in cognition after CABG. The cause of this dysfunction has not been determined. Although some studies suggest that avoiding CPB during cardiac surgery decreases the risk of neurologic injury [Murkin 2000], other reports suggest no relationship between the magnitude of the inflammatory response and severity of cognitive change [Westaby 2001]. Other factors therefore may play a role. One possible factor is the liberation of particulate emboli from the proximal aorta during manipulation. Although OPCAB obviates the need for aortic cannulation and cross-clamping, many surgeons place a partial occlusion clamp on the ascending aorta to allow construction of the proximal anastomoses. New automated anastomotic devices that allow grafts to be attached to the pressurized ascending aorta without partial occlusion or CPB may, when combined with OPCAB, have a favorable impact on the incidence of postoperative neurocognitive dysfunction.

Saphenous vein graft (SVG) attrition continues to be a significant problem after CABG. Approximately 50% of SVGs become occluded by five years, and 50% of patent grafts have significant disease. This has led to the increased use of arterial grafts in many surgeons' practices. Furthermore, work is ongoing to develop synthetic graft materials. These efforts include

the use of autologous tissue (pericardium), xenograph tissue (small bowel submucosa), and prosthetic material coated with autologous cells. The initial goal of these efforts has been to provide conduits for patients for whom vein grafts are not available. It is possible, however that one or more of these efforts may yield a superior graft material.

Closed-chest heart surgery is being developed to minimize the trauma of surgical access. Several investigators have demonstrated that LIMA harvest and beating-heart CABG is an attainable goal with currently available robotic assist systems. Although this technique is now only for the few and the daring, with continued refinement of the techniques and of the robots themselves, closed-chest multivessel OPCAB may become a viable approach. Automated "one-shot" distal anastomotic devices, improved closed-chest stabilizers, and other devices may have a significant impact on this development. New instruments, including thoracoscopic ports with integrated tremor reduction technology, may actually make closed-chest, non-robotic CABG possible. A procedure that requires no incision, that can be performed on the beating heart without cardiopulmonary bypass, and that provides long-term results comparable to current conventional CABG would be an extremely attractive option for many patients.

It is likely that CABG will continue to play an important role in the treatment of coronary artery disease for at least a decade more. If in the final analysis, CABG ends up in the textbook of obsolete procedures, in all likelihood it will be because of advances in the understanding and prevention of atherosclerosis. As the genetic and biochemical bases of coronary artery disease are elucidated, therapies directed at prevention will become the primary tools used in patients at risk for atherosclerosis.

Implants and Xenotransplantation

Another area of growth and development within our specialty is the surgical treatment of the failing heart. Continued technological improvements in the design of ventricular assist devices are making these devices safer, easier to implant, and useful for a broader range of patients. Also in development are devices designed to favorably alter the shape or volume of the left ventricle by providing structural support to the walls of the ventricle, thereby lowering wall stress and improving cardiac efficiency. Finally, with further pharmacological and biotechnological advances, the results of cardiac transplantation will continue to improve. Though cardiac transplantation is severely limited by donor availability, there are extensive, ongoing research efforts aimed at increasing the donor pool through xenotransplantation. Although the results thus far are mixed, xenotransplantation offers a promising, albeit distant, solution to the donor pool problem.

SUMMARY

While it is true that there are, and will continue to be, new therapies to treat heart disease using catheter-based technologies, the future of cardiac surgery is bright. With the proven efficacy of CBTs, we must embrace these new technologies as significant improvements even as we accept the challenge to keep pace with CBT advances by improving our surgical results, minimizing the adverse sequelae of our procedures, and developing novel therapies for the treatment of heart disease. In so doing, we will not only secure the future of our specialty but, most importantly, will continue to improve the lives of those afflicted with heart disease.

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