Reducing the Invasiveness of Cardiac Surgery: Anesthetic Implications

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In the 1960s adoption of cardiopulmonary bypass (CPB) and the associated still surgical field for coronary artery bypass graft (CABG) surgery resulted in CABG being adopted as the standard treatment for severe coronary artery disease. In the 1970s and 1980s this procedure became one of the most frequent of all surgeries, with refinements in cardioplegia techniques, conduit preparation and choice, and many aspects of perioperative management leading to improved outcomes. In 1996 more than 350,000 CABG procedures were performed in the United States (1). Parallel with these developments in surgery have come tremendous advances in catheter-based techniques performed in the cardiac catheterization laboratory. Coronary angioplasty with or without stent exceeded the number of CABG procedures in 1996 (1). The gap is now widening, with the number of CABG procedures decreasing and angioplasty with stent increasing, (2) and the possibility that drug-eluting stents will further reduce the need for surgery by 10%–15% (personal communication, Robert Guyton, MD).

In response to the challenge by the interventional cardiologists, cardiac surgeons have explored many avenues (Table 1) in a quest to reduce the physiologic trespass of surgery. The most widespread of these is a return to performing CABG on the beating heart without the benefit of CPB to reduce complications associated with aortic cannulation and clamping and the response to artificial circulation. Development of stabilization techniques and devices in the last 10 yr has greatly facilitated this process, with many cardiac surgeons now doing a proportion of their CABG procedures "off pump." (3) Anesthetic management, including support of the circulation during cardiac manipulation, and cardiac monitoring have evolved to meet the need for CABG surgery without artificial circulation. Another avenue being explored is the use of limited or alternative incisions, both for CABG and for valve replacement. These range from "port access" CABG or valve surgery performed through a small incision, facilitated by endoscopic devices and specially designed cannulation and cardioplegia apparatus, to off-pump CABG and valve replacement through smaller incisions. Perhaps the most exciting approach has been the use of robotic technology to enhance control of surgical instruments. This has been used for CABG and valve procedures with CPB and also for off-pump CABG (4). These procedures may require anesthesiology techniques not usually associated with cardiac surgery (e.g., one-lung anesthesia) as well as modifications in monitoring and transcutaneous pacing/defibrillation techniques to deal with limited surgical access. Finally, there is now substantial experience with transmyocardial laser techniques for revascularization, either as an isolated procedure without CPB performed through a left thoracotomy incision, or as a supplement to traditional CABG surgery (5). These procedures are not associated with early benefit; indeed, the early effects may be a worsening in function, necessitating close monitoring and hemodynamic support.

Alternatives to Sternotomy

Sternotomy usually requires a large skin incision, and recovery to the point of normal use of the upper limbs takes 6–8 wk. Morbidity related to great vessel cannulation, aortic cross-clamping, and CPB represent a greater medical consideration than morbidity resulting from sternotomy. However, in the mind of the patient the cosmetic and functional aspects of sternotomy predominate. To address these cosmetic and functional concerns, a number of alternative approaches have been tried. In a minority of patients there may be specific surgical reasons to avoid sternotomy (e.g., previous sternotomy with intact internal mammary artery [IMA] graft, chest wall deformity).

Surgical approaches to CABG without CPB include left anterior thoracotomy to access the left anterior descending (LAD) artery and diagonal vessels, right thoracotomy for the right coronary artery (RCA), and a variety of parasternal or partial sternotomy incisions. A substernal or subxiphoid approach has also been described (6). The small left thoracotomy approach has been termed "minimally invasive direct coronary artery bypass" or MIDCAB. In high-risk patients with multi-vessel disease, surgical revascularization of the LAD through a MIDCAB procedure and angioplasty of other vessels has been reported (7).

Table 1. Less Invasive Approaches to Heart Surgery

With Cardiopulmonary Bypass
Alternatives to Midline Sternotomy
Partial Sternotomy
Parasternal incision
Port-access with mini-thoracotomy
Port-access with robot-assisted endoscopic instrumentation
Without Cardiopulmonary Bypass
Midline Sternotomy ("OPCAB")
Alternatives to Midline Sternotomy
Small left lateral thoracotomy ("MIDCAB")
Right thoracotomy (For right coronary artery)
Parasternal incision
Subxiphoid incision
Robot-assisted endoscopic instrumentation
Transmyocardial laser revascularization
Isolated procedure through left thoracotomy
Supplement to on-pump CABG

CABG = coronary artery bypass grafting.

Most surgeons find alternative approaches fail to provide optimal access to all regions of the myocardium and may foster an incomplete revascularization that would have been more complete through a sternotomy. Alternative approaches require the knowledge of different surgical techniques, use of different instruments, and coping with limited exposure. Not surprisingly, early reports (and even some more recent reports) suggest graft patency may be compromised because of problems with harvesting of the IMA as well as difficulty with the anastomoses. Issues of long-term complications from unusual incisions as well as increased early postoperative pain have also dampened enthusiasm for many of these approaches. Currently the majority of off-pump CABG procedures are done with traditional sternotomy.

Port-access surgery was described in 1996 by the Stanford group (8), with the goal of using endoscopic techniques, percutaneous cannulation, and a small lateral thoracotomy incision to perform CABG with CPB. Subsequently, valve replacement surgery was performed with this technique. Technical difficulties, complications associated with cannulation techniques, increased time requirements, and the lack of outcome benefit have limited the appeal of this approach. A recent publication confirms the difficulty with the technique, but acknowledges its contribution in moving cardiac surgery towards endoscopic techniques (9).

"Minimally invasive" valve replacement surgery has been performed through partial sternotomy or thoracotomy incisions (10,11). Surgeons have used instruments and cannulae that were designed for port-access surgery to facilitate access to specific cardiac valves through the small incisions. The proposed advantages of a better cosmetic result and potential for earlier recovery must be weighed against the increased difficulty of the surgery and limited access to deal with complications such as bleeding. As in MIDCAB, these approaches are not widely used.

True endoscopic cardiac surgery can be performed with the use of robotic, computer-assisted instrumentation (12,13). If CPB is required, "heart port" cannulation techniques are used, then the robot-assisted instruments are used for the CABG or valve procedure. Early reports in patients attest to the feasibility; however, the robotic systems are very expensive and the procedures are time consuming. Vascular anastomosis is painstakingly slow; development of automated anastomoses from a number of different manufacturers has the potential to facilitate rapid, high-quality coronary grafting (14). These latter devices may permit robotic off-pump CABG.

Anesthetic Implications

Angioplasty Versus Surgery

It may be that the most important "anesthetic implication" is the change in the CABG surgery population both in nature and number. The age, degree of left ventricular dysfunction, and coexisting illness of patients presenting for CABG continues to increase (15), whereas the number of patients referred for surgery is either flat or decreasing (1,2). As providers of care for patients with coronary artery disease it is important that anesthesiologists are familiar with the data on which treatment decisions are based. Three randomized trials of multivessel angioplasty with stenting versus surgery have been recently published (16–18). Table 2 summarizes these studies; the two larger ones show either no difference or a reduction in mortality with CABG; all three show a significant reduction in need for reintervention. This need has decreased with time and is predicted to decrease further with immunosuppressive treatment of stents (19). The two larger studies demonstrate a reduced need for antianginal medication and lower incidence of angina with surgery (not reported in the third), another recent publication reports improved recovery of health status with CABG versus angioplasty, attributed to the reduced need for reintervention (20). Of major importance is the fact that the standard for patency and survival benefit is an IMA graft to the LAD. This graft, done in the absence of other significant disease, confers a 15-yr intervention-free survival of 90% (21). Alternative surgical strategies and angioplasty procedures must be held to this standard for comparison. The IMA-to-LAD graft is the most critical part of the CABG procedure. In summary, although angioplasty with stent continues to increase in frequency as an alternative to CABG, the standard for improvement in symptoms,

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Table 2. Multivessel Angioplasty/Stent Versus CABG: Recent Randomized Trials

	Serruys et al. Europe/South America	Rodriguez et al. Argentina	SoS Trial Europe/ Canada
Year Published	2001	2001	2002
Journal	N Engl J Med	J Am Coll Cardiol	Lancet
Enrolment dates	4/97–6/98	10/96–9/98	11/96–12/99
Angio:CABG (n)	600:605	225:225	488:500
% 3–vessel disease (angio:CABG)	30:33	55:58	38:47
OUTCOME (angio:CABG)			
% Death	2.5:2.8 (12 mo)	3.1:7.5 (900 day)	3:1 (1 yr); 5:2 (3 yr)
% CVA	1.7:2.1 (12 mo)	0:0.9 (900 day)	1:2 (1 yr)
% MI	6.2:4.8 (12 mo-all)	0.9:5.7 (30 day Q wave)	5:8 (1 yr Q wave)
% Freedom from Repeat Procedure	79:96.2 (12 mo)	83.2:95.2 (900 day)	79:94 (2 yr)

CABG = coronary artery bypass grafting; CVA = cerebrovascular accident; MI = myocardial infarction.

freedom from reintervention, and, in most studies, long-term survival is still CABG.

CABG Without Cardiopulmonary Bypass

Approximately one-third of the CABG procedures done in the United States are now done without CPB (3), and the majority of these are done through a median sternotomy (OPCAB) to allow the use of standard, proven techniques for harvest of the IMA and access to all coronary distributions. Although MIDCAB comprised a significant proportion of early off-pump procedures, this is now done in selected patients in a small number of centers. Anesthetic considerations for MIDCAB differ from those for OPCAB because of the potential need for one-lung anesthesia, the positioning requirements for a left lateral thoracotomy, and the lack of access to the heart. As the procedure is potentially shorter with less cardiac manipulation (usually only IMA-to-LAD grafting), recovery may be more rapid. These considerations are discussed by Gayes et al. (22), although this publication describes practice in 1996 before the widespread use of modern epicardial stabilizers.

Indications

An ever-increasing number of articles in the cardiac surgery literature attest to the benefits of OPCAB. The majority of these reports are historical presentations of surgical experience over time in selected patients. They do support the contention that short-term outcomes in the patients selected for OPCAB versus on-pump CABG compare favorably, but long-term graft patency data are not available. Sewing coronary vessels on the beating heart is technically challenging and not necessarily appropriate for all surgeons (23). There are two published randomized trials, (24,25) with another soon to be published (J. Puskas, presented at the Society for Thoracic Surgeons, 2002) and preliminary data from a fourth (N. E. Khan, presented at the American Heart Association, November 20, 2002). The total number of patients in these four trials is approximately 1000. All of these trials indicate that mortality and major outcomes from on-pump or off-pump CABG are similar, with a reduction in enzyme release, bleeding and length of stay a consistent finding with OPCAB. Although reduction in stroke has been one of the proposed benefits of the technique (as a result of avoidance of aortic cannulation and cross-clamping), these studies do not demonstrate this benefit.

Preoperative Assessment

For on-pump surgery anesthetic management is not greatly affected by the coronary anatomy, apart from certain conditions such as high-grade left main disease. For OPCAB the ability of the patient to tolerate brief or extended occlusion of target vessels is critically dependent on both the target and the surrounding vasculature. For example, occlusion of the LAD for a tightly stenosed distal lesion is likely to be well tolerated for two reasons: the lesion is distal, and collaterals have probably developed. However, occlusion of the same vessel for a less tight, proximal lesion may be disastrous, especially if there are high-grade occlusions of neighboring vessels. The neighboring territories may be collateralized from the LAD, and occlusion of the latter vessel may cause global ventricular dysfunction, mitral regurgitation, and acute failure. Thus, to prepare for the likely consequences of coronary occlusion, the anesthesiologist must understand the functional coronary anatomy, as well as the surgical plan (i.e., which vessels will be occluded in what order, planned use of specific anti-ischemic strategies).

Monitoring

The monitoring strategy for OPCAB has evolved with the procedure. Initial concern regarding ischemic ventricular dysfunction prompted a desire for "maximum" monitoring: transesophageal echocardiography (TEE) and the pulmonary artery catheter (PAC). However, surgeons were only performing single or double bypasses, often in patients with normal ventricular function, and it became apparent that extensive monitoring was not actually warranted. As the number of vessels bypassed has increased, the intraoperative challenges have increased. When multiple grafts are contemplated in a patient with reduced ventricular function, a PAC may be useful both intraoperatively and in the postoperative period. TEE provides immediate and specific information concerning regional and global ventricular function and can detect mitral regurgitation resulting from positioning (26). It also provides reassurance with regard to restoration of normal function after periods of coronary occlusion and grafting, although this information must be viewed with some skepticism, as TEE does not assess adequacy of the anastomosis. Recently high-frequency (i.e., high-resolution) epicardial echocardiography has been evaluated as a tool for evaluation of coronary vessels during OPCAB (27). Monitoring choices for less invasive approaches including OPCAB are summarized in Table 3.

There are limitations to all monitoring techniques. When the heart is supported or displaced from its normal "lie" in the chest the ECG may show very small complexes with altered polarity and it may not be possible to obtain TEE images. Similarly, despite significant regional ischemic dysfunction (visible on the TEE), there may be little or no change in pulmonary artery pressures. The time and attention required to obtain good TEE images can be distracting. If the preoperative discussion with the surgeon indicates a brief procedure in a patient with preserved ventricular function, then a clear, calibrated 2-lead ECG tracing, preferably with ST segment trending, and a central venous catheter is probably adequate monitoring. At the other extreme, a plan for multi-vessel grafting in a high-risk patient with poor ventricular function might warrant the use of both TEE and a PAC.

In early reports of MIDCAB, use of a continuous cardiac output and mixed venous saturation PAC was suggested (28) and the need for pacing (e.g., via the PAC) was considered. A more recent report suggests that neither pacing capacity nor PAC data were necessary (29). As access to the heart is limited by any approach other than sternotomy, surface patches that permit defibrillation and pacing are recommended.

Anesthetic Technique

If the surgery is well tolerated, the trachea can be extubated at the end of surgery; the anesthetic technique must be tailored for this eventuality. In one recent report thoracic epidural anesthesia with propofol/muscle relaxant was used (30), and in another, five patients were given "high thoracic" epidural anesthesia with sedation (midazolam), as well as upper extremity blocks (axillary or musculoskeletal nerve) for radial artery harvest to allow grafting through mini-thoracotomy incisions (31). The editorial comment suggested this latter approach "seems to offer more risk with little advantage" (32). General anesthesia using a vapor- or propofol-based technique similar to that used for "fast track" on-pump surgery, which allows immediate or early postoperative awakening, is appropriate for this procedure.

Temperature lost during surgery cannot be restored by the heart-lung machine; warming the operating room and mattress before the patient arrives, placing warm air blankets over the patient's legs (after vein harvesting) and head, and warming IV fluids help prevent hypothermia. The devices that heat and fan air into forced air devices have very fine filters (fraction of a micron) to prevent airborne contamination. Cardiac anesthesiologists are not used to paying attention to temperature before CPB; it is important to keep the patient warmed and covered before surgical "prep and drape," and to use the warm air blankets as soon as possible.

Hemodynamic Management

Prevention and treatment of hypotension, low cardiac output and dysrhythmias is a major focus of anesthetic management; this is especially true when the heart is displaced for performing grafts in the circumflex artery distribution. Both in the laboratory and in clinical practice, volume loading and the head-down position (i.e., "preload augmentation") can help maintain cardiac output and perfusion pressure when the heart is displaced (33). Opening or release of the mediastinal pleura on the right (to prevent right ventricular compression and kinking of the great veins) appears to help in this circumstance. It may also be useful to achieve a slightly elevated perfusion pressure by reducing the level of anesthesia or by administering a vasopressor before the surgeon occludes the target vessel. Should hypotension occur, there should be no delay in quickly progressing to a potent vasopressor/inotropic drug such as epinephrine or norepinephrine. Close observation of the surgical field and open communication with the surgeon are essential during periods of coronary occlusion. Immediate availability of CPB is necessary; the surgeon can usually predict the patients most likely to need this modality. For high-risk patients the surgeon may choose to place an intra-aortic balloon pump after induction of anesthesia, or, especially for nonsternotomy approaches, expose or even place catheters/wires in the groin vessels.

Inducing Bradycardia. As reports of off-pump procedures began to appear, the need to keep the heart rate slow was a common theme. The slower the heart, the easier things would be for the surgeon. With the widespread use of epicardial stabilizing devices that immobilize the heart at the site of anastomosis, the

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Table 3. Monitoring approaches for Less Invasive Cardiac Surgery

Monitor	Advantages	Disadvantages	Comment
ECG	Universal Simple Inexpensive Recognized criteria	Insensitive Position dependent (lead and heart)	Best if multi-lead Should be calibrated ST segment trending helpful
Central Venous Pressure	Simple Inexpensive	Insensitive for LV dysfunction No cardiac output	Necessary for infusions Affected by position of heart, patient Use of "introducer" allows rapid PAC insertion
Pulmonary Artery Catheter (PAC)	LV filling pressure Cardiac output Options may be helpful (SVO_2, CCO, pacing)	Expensive Insensitive for acute regional dysfunction Postoperative nuisance in straightforward cases	Controversial monitor Prolongs ICU stay due to "abnormal numbers" Gold standard for guiding therapy in complex cases
Transesophageal Echocardiography	Gold standard for acute ischemia Verify restoration of function Guide surgical cannula placement Guide TMLR	Expensive User dependent Distracting May not have good view of heart Only intraoperative	Requires expertise Increasingly viewed as essential tool especially when surgical access limited
Cardiac output (Bioimpedance, aortic flow, CO_2 rebreathing)	Less invasive than PAC Can give beat-to-beat flow	Expensive No measure of LV filling May be user dependent	Bioimpedance not reliable with open chest. May not give readings in all patients

ICU = intensive care unit; LV = left ventricular; TMLR = transmyocardial laser revascularization; CCO = continuous cardiac output; SVO_2 = mixed venous oxygen saturation; ECG = electrocardiogram.

need for bradycardia has almost disappeared. All drugs that slow the heart also depress its function, and with slower heart rates and larger stroke volumes there may actually be greater motion in the surgical field. In some cases there may be a request for pacing to reduce the heart size, or a need for pacing when surgery affects the blood supply to the sinus node (RCA distribution). Alternatively, it can be argued that the heart should be kept as slow as possible during periods of ischemia. Thus, the use of β-blocking drugs or calcium channel blockers versus pacing needs to be individualized to the patient's hemodynamic state and ventricular function. A muscle relaxant other than pancuronium should be considered in patients who are not already β blocked or who have a heart rate >90 bpm before induction.

Anticoagulation. Anticoagulation strategies are institution or even surgeon-specific. Some surgeons request partial heparinization (e.g., heparin 100–150 U/kg to achieve an activated clotting time of 250–300 s); however, others request standard CPB doses of heparin and cautious reversal with protamine, if possible to a level slightly above control. This is a result of concern for unpredictable graft occlusion and the postoperative hypercoagulable state that occurs after other major surgery not involving CPB. This theoretical concern needs to be balanced with the problem of bleeding in the partially reversed patient. One recent report documented evidence for increased procoagulant activity the day after OPCAB, and suggested use of adequate heparin to keep the ACT >300 s intraoperatively with no reversal unless there is bleeding (34). A review of thrombotic complications after 500 OPCABs versus 1476 on-pump CABG patients showed no difference (35).

Techniques to Reduce Ischemic Complications

Ischemic Preconditioning. Originally described in an animal model in 1986, the observation that a brief period of ischemia conferred relative protection against a subsequent more prolonged ischemic insult has been confirmed in humans (36). There has been some interest in applying this technique for the 8–12 min coronary occlusion that is necessary for OPCAB. However, experimental work has failed to demonstrate a significant benefit. Administration of 1 MAC end-tidal isoflurane provides "pharmacologic preconditioning" in a coronary occlusion model (37); however, this has not been studied for OPCAB.

Perfusion Assistance. Quest Medical Inc., has developed a perfusion device designed to maintain normal or high levels of blood flow down vein grafts, independent of the patient's blood pressure, after the distal anastomosis but before the proximal anastomosis has been completed. This allows the surgeon to perform the distal grafts first, which is the traditional approach for on-pump surgery, and permits not only supraphysiologic flow but also provides the potential for additives (such as vasodilators or inotropic drugs). Use of the pump requires full heparinization, and an arterial access cannula (9-gauge). A report from our institution suggested the device facilitated off-pump surgery by promoting rapid recovery, enhancing hemodynamic stability, and by providing increased flexibility in the sequence of grafting (38).

Anti-Ischemic Drugs. Although infusions of anti-ischemic drugs may seem an attractive idea, every such drug has hemodynamic consequences. Nitroglycerin infusions will work against the necessary preload augmentation described above; β-blockers and calcium channel blockers are negative inotropes. As the hemodynamic response to cardiac positioning and ischemia is unpredictable, prophylactic use of vasodilating and negative inotropic drugs may cause more problems than they prevent. When spasm of an arterial conduit is a concern, recent work suggests that nitroglycerin, rather than a calcium channel blocker, is the drug of choice (39).

Surgical Techniques to Reduce Ischemia. Surgical techniques to reduce the period of ischemia include performance of proximal grafts first (to allow immediate flow after completion of the distal anastomosis), and use of intra-coronary shunt devices. Disadvantages to these techniques are, in the former case, uncertainty concerning length and final position of vein grafts, and, in the latter case, the potential for endothelial trauma.

Port Access Techniques for Cardiopulmonary Bypass

Though seldom used as originally designed (valve or CABG surgery through a mini-thoractomy), the "Heartport" cannulation techniques may be used to provide CPB for endoscopic, robotic procedures (4). This requires femoral venous cannulation and often a pulmonary artery vent to augment venous return, and either femoral artery or transthoracic aortic cannulation with a modified cannula incorporating an "endoclamp" or inflatable occlusive balloon. This aortic device also has a distal port for the administration of cardioplegia. These catheters cannot be placed without TEE imaging, and they also require frequent or continuous TEE monitoring to assure the aortic device stays in the correct position. This requires a degree of expertise in TEE and teamwork with the surgeon that is seldom demanded of the anesthesiologist. Similarly to MIDCAB, one-lung anesthesia may be required, and access to the heart is very limited requiring the placement of cutaneous patches to permit pacing and defibrillation.

Robot-Assisted Endoscopic Procedures

For endoscopic work on the heart, the left lung must be deflated and carbon dioxide insufflated. Alternatively, high frequency ventilation can be used (4). Placement of a double-lumen tube may be required, and changing the tube at the end of the procedure may be desirable. The effects of carbon dioxide insufflation, changes in intrathoracic pressure, and manipulation of a double-lumen tube on gas exchange and cardiac function must be closely monitored. The range of robotic cardiac surgery that has been performed to date is reviewed by Czibik et al. (40).

Positioning the patient for port-access or endoscopic intrathoracic surgery requires that special attention be paid to balancing surgical needs with the potential for upper extremity soft-tissue or nerve injury. The duration of these procedures makes this an important consideration. Prevention of traction or pressure on nerves is a shared responsibility of the surgery and anesthesiology teams when positioning and padding the arms. This is especially true when they are to be elevated above the plane of the body or the head.

Transmyocardial Laser Procedures

Transmyocardial laser revascularization (TMLR) is a procedure reserved for patients unsuitable for coronary angioplasty or CABG. It is most often used to supplement CABG, especially reoperations, for regions of the myocardium without adequate vessels for grafting. Regardless of the type of laser used (carbon dioxide [CO_2], holmium [YAG], or xenon chloride [XeCl]), the goal is to use the energy of the laser to create channels through the myocardium via tissue destruction. The anesthetic implications relate to laser safety, both for the patient and caregivers, monitoring of intracardiac laser penetration and avoidance of cardiac tissues, and the likely need for hemodynamic support. Anesthetic management and early postoperative care for laser revascularization procedures are reviewed by Grocott et al. (41) and Thrush (42). For isolated TMLR, anesthetic considerations are similar to those for MIDCAB as the procedure is done through a left lateral thoracotomy with the aid of left lung collapse. Transcutaneous pacing/defibrillation may be necessary, and the patient must be positioned for groin access in case of the need for urgent CPB. Unlike MIDCAB there is no immediate benefit; postoperative ventricular dysfunction and dysrhythmias are common.

The laser may damage intracardiac structures, especially the mitral valve, and bubbles generated by the laser beam have the potential for embolization. Nitrous oxide should probably be avoided. These considerations make TEE monitoring an essential part of the procedure, both to validate intramyocardial perforation by the laser (through visualization of the bubbles), and to assess intracardiac structures and function.

Summary

Less invasive approaches to cardiac surgery now comprise a significant proportion of the cardiac surgical caseload. Many of these approaches significantly limit access to the heart and require the anesthesiologist to understand the coronary anatomy and surgical plan, to prepare to deal with cardiac dysfunction or dysrhythmias without immediate availability of CPB, and to have expertise in TEE as well as other monitoring modalities. At the same time, one of the expectations is early recovery and reduced length of stay. The challenges are great, and more than ever before the anesthesiologist is a key player in providing the great benefit to these patients with life-threatening cardiac disease.

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