Get a handle on the new technology for treating cardiovascular disease.

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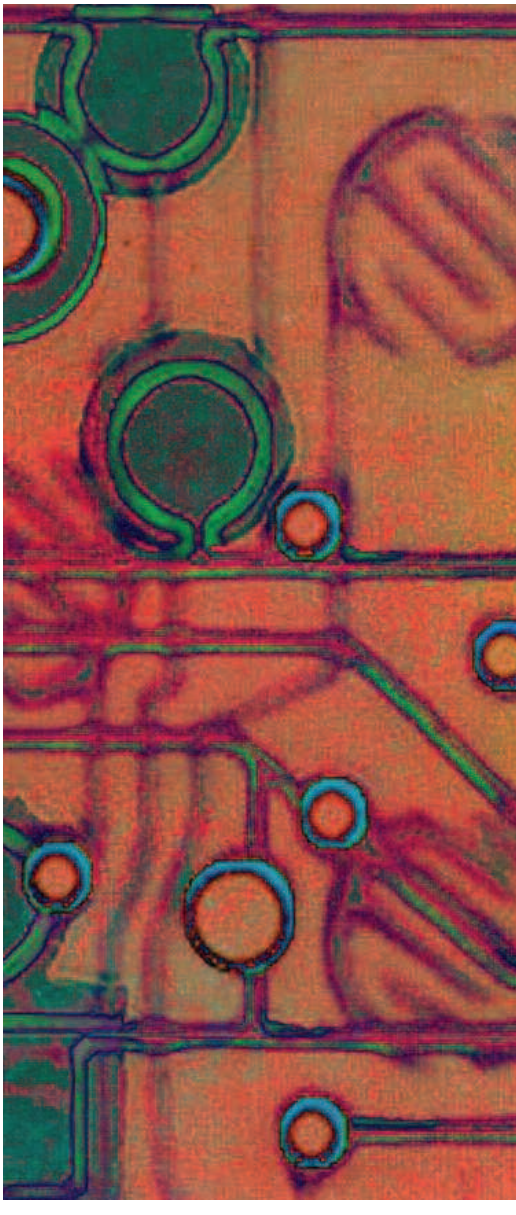

Cardiovascular disease (CVD) is the leading cause of death in the United States, with an average of 2,500 Americans dying from it each day, or one death every 35 seconds.[1] In 2003, 37.3% of all deaths were from CVD.[1] The reported mortality percentage from CVD is further subdivided into individual disorders that include, among others, hypertension, heart failure, stroke, and coronary heart disease—the most common. Cardiovascular disease is costly, with $11.6 billion dollars paid to Medicare beneficiaries in 2001.[1] Technologic advances in the cardiac catheterization laboratory and with cardiovascular surgery have expanded management options. This overview and update of selected procedures used in the treatment of CVD in adults will include percutaneous coronary intervention (including drug-eluting stents), off-pump coronary artery bypass surgery, and minimally invasive heart valve surgery.

Percutaneous coronary intervention

The term percutaneous coronary intervention (PCI) refers to a group of procedures performed in the cardiac catheterization laboratory to treat atherosclerotic lesions within the coronary arteries. The group includes percutaneous transluminal coronary angioplasty (PTCA), coronary atherectomy, thrombectomy, and coronary stents—both bare-metal and drug-eluting. In 2003, an estimated 664,000 PCI procedures were performed on 652,000 patients in the United States.[1] In 1977, Andreas Grüntzig performed the original PCI procedure, a PTCA.[2] This procedure increases the coronary artery lumen diameter through inflation of a balloon mounted on a catheter end. The balloon inflation causes the atheromatous plaque to fracture and compress into the vessel wall at various depths and lengths. Although PTCA increases the internal lumen diameter and improves coronary blood flow, it causes damage to the vascular endothelium. This injury results in the acute complications of acute vessel closure or thrombosis within 24 hours of the procedure. The long-term complication of restenosis in both conditions may require a repeat revascularization procedure. Of major importance in predicting the success of the procedure are the angiographic characteristics of

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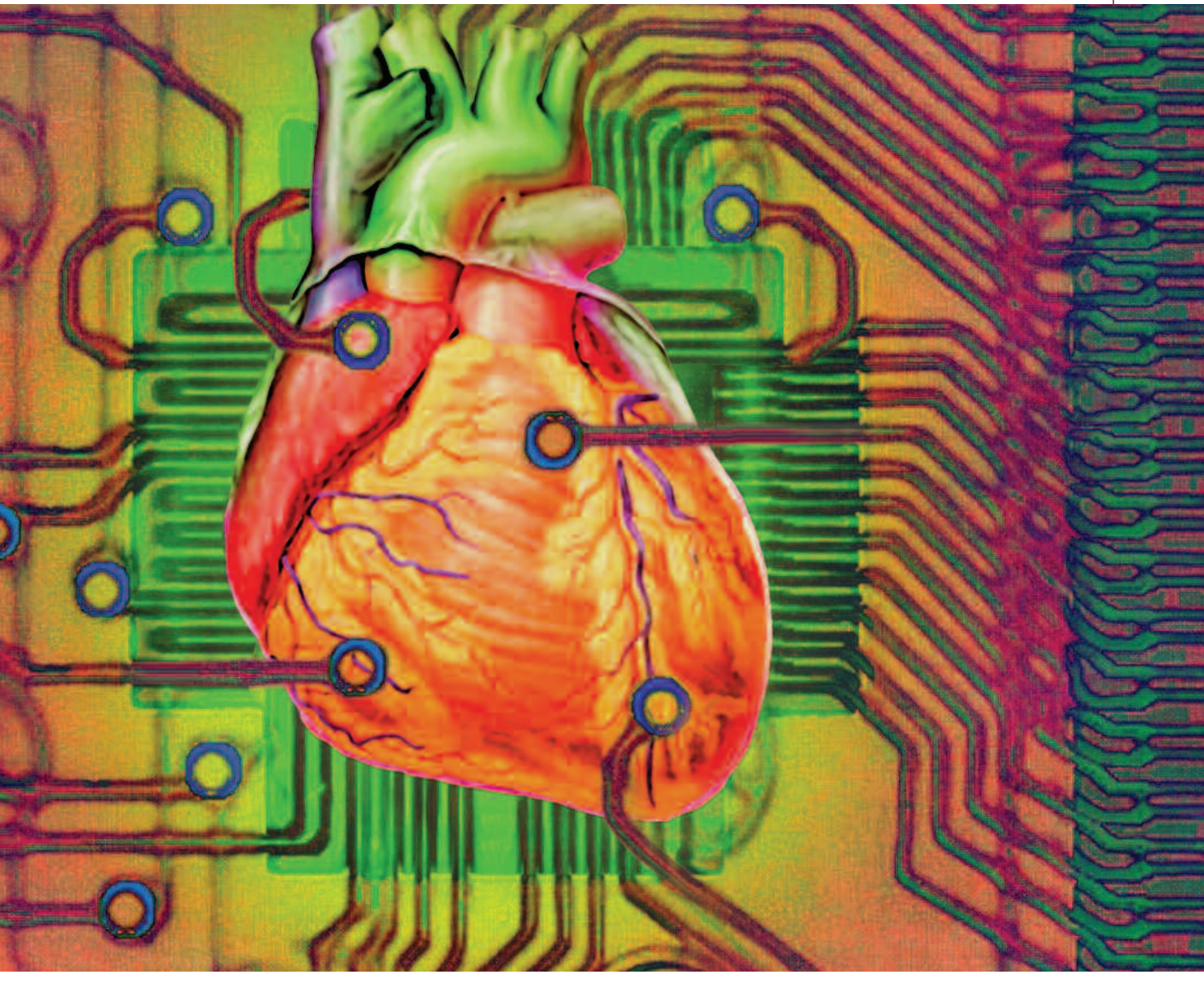
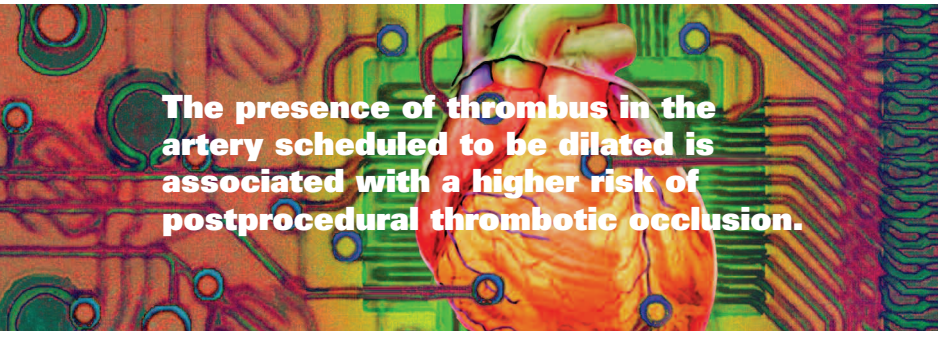


the lesion set to be dilated. Restenosis is the narrowing of a treated vessel over time, typically occurring the first 6 months after the procedure. It's the most common complication following PTCA.[3] Renarrowing within the first few days after an angioplasty procedure usually represents abrupt closure rather than restenosis of the vessel. Restenosis is thought to stem from a negative arterial remodeling process (arterial constriction) and neointimal hyperplasia along with several other mechanisms.[4] The presence of thrombus in the artery scheduled to be dilated is associated with a higher risk of postprocedural thrombotic occlusion. The incidence of acute vessel closure post-PTCA has been reported at approximately 2% to 3%, with restenosis rates up to 40% within the first 6 months.[5] Currently, PTCA is usually used in conjunction with other PCI techniques.



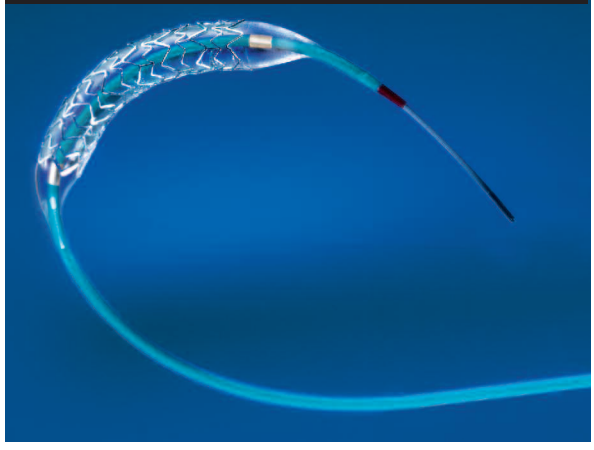
In the 1980s, advances in PTCA catheters and balloons allowed for expanded use in various types of coronary artery lesions. The problem of restenosis remained. In 1990, the introduction of coronary atherectomy (plaque removal) catheters was hoped to reduce the incidence of restenosis by controlling the injury through systematic debulking of the atheroma.[6]

Directional coronary atherectomy (DCA) uses a hollow steel chamber with an opening that's pressed against the lesion by the inflation of a balloon on the opposite side. A cutter within the hollow chamber excises the atheroma that protrudes into the window, and is subsequently removed.[6] A rotational atherectomy catheter (Rotablator) is used in heavily calcified coronary lesions. This catheter, usually made of stainless steel, has an olive-shaped metal burr end that's embedded with diamond chips. When the burr is positioned over the lesion, it's attached to a flexible drive shaft. A compressed-air turbine rotates the shaft, pulverizing the calcified plaque into particles 2 to 5 microns in diameter, to be removed by phagocytosis.[6] The restenosis rate from intimal hyperplasia was found to be the same as from PTCA.[6] These interventions are useful in several subsets of patients with coronary artery disease (CAD). Whereas DCA is used to physically remove plaque from the vessels, the Rotablator is used to ablate the plaque in situ. When introduced into the stenosed area of the vessel, the Rotablator's fine elliptoid tip rotates rapidly, grinding atheroma into minute fragments.

A secondary PCI technique is the thrombectomy catheter. This catheter is used to remove clots that are obstructing either a native coronary artery or bypass graft, commonly seen in an acute myocardial infarction. The most prevalent thrombectomy device is the AngioJet catheter. The AngioJet uses high-velocity-pulsed saline jets within the catheter to create a vacuum that draws in the thrombus. The clot is pulverized into microscopic particles that are propelled back out of the catheter and into the pump.[5] This reestablishes coronary luminal blood flow prior to further interventional procedures.

A coronary stent is a metallic endovascular prosthetic device mounted on an angioplasty balloon. The balloon is inflated, allowing for expansion of the attached stent. When the balloon is deflated and removed, the expanded cylinder-shaped stent remains to provide structural support to maintain the coronary lumen patency. The use of stents developed as a result of complications seen in PTCA. In 1993, the first Federal Drug Administration (FDA)-approved coronary stent—a bare metal stainless steel wire coil Gianturco-Roubin Flex-Stent by Cook, Inc.—was released.[7] The initial indication for use was to act as a bail-out device in treating acute vessel closure during the angioplasty. More recent usage focused on reducing the arterial remodeling associated with restenosis.[7] Indications include restenosis, dissection, abrupt closure, residual stenosis, or reopened total occlusion. Intracoronary stenting has proved to be a successful method of circumventing emergency coronary

TAXUS Express2 drug-eluting stent mounted on a balloon delivery system



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artery bypass graft (CABG) surgeries after acute vessel closure in angioplasty procedures. Indications for coronary stent use have expanded to include acute closure or dissection during angioplasty, primary treatment of acute coronary syndromes, primary reduction in restenosis in de novo lesions within vessels 3 mm in diameter and larger, and stenosis within a saphenous vein graft.[3]

In 2003, over 84% of all PCI patients received a stent.[1] Since its inception stent technology has evolved to encompass multiple designs and sizes, using various metals that include stainless steel and tantalum.[7] The incidence of restenosis is reduced with the use of bare metal stents (BMS) in comparison to balloon angioplasty. In 1994, the In-Stent Restenosis Trial Investigators reported a 31.6% restenosis rate for stents compared to a 42.1% rate for angioplasty after 6 months.[8] This reduction was the result of the increased coronary lumen size, not a decrease in neointimal hyperplasia development.

The BMS itself may cause vessel injury. The resulting inflammatory response stimulates endothelial smooth muscle proliferation. This hyperplasia extrudes through the struts, causing a phenomenon known as in-stent restenosis.[9] To combat the in-stent restenosis that may occur with a BMS, a PCI technique known as brachytherapy was developed. Local radiotherapy with beta and gamma emitters is shown to markedly reduce the risk of restenosis following stent placement. This form of therapy has a major beneficial impact in preventing restenosis occurring with original stent placement. The risk of restenosis following brachytherapy suggests that in the first year, the incidence is approximately 5% to 15%. Iridium-192 or yttrium-90 have been used for gamma and beta radiation, respectively.[10] Problems have been identified with long-term follow-up that include edge restenosis at the distal ends of the radiated segment, later-stage development of thrombosis, coronary aneurysms, and rarely pseudoaneurysms. Long-term antiplatelet therapy has been recommended in the treatment, including aspirin and clopidogrel (Plavix).

A drug-eluting stent (DES) delivers a substance or medication directly to the coronary lesion. This inhibits the development of intimal hyperplasia through interference in the cell cycle, thus preventing in-stent restenosis.[5] CYPHER, a sirolimus-eluting stent (Cordis Corporation–Johnson and Johnson), was first released in 2003. This was followed in 2004 by TAXUS, a paclitaxel-eluting stent (Boston Scientific Corporation). These are the only FDA-approved drug-eluting stents in the United States at this time. A DES typically consists of three components: a metal scaffold, a polymer, and the drug. The metal is usually stainless steel. The medium that promotes diffusion, or eluting, of the drug into the lesion is a polymer. The polymer is combined with the drug using various techniques, and the mixture is applied uniformly to the stent.[9] Deployment of a DES follows the same technique as a bare metal stent. (See TAXUS Express drug-eluting stent mounted on a balloon delivery system.)

The drugs used to coat a DES are classified into four categories: immunosuppressive, antiproliferative, anti-inflammatory, or prohealing. Paclitaxel is an antiproliferative medication, originally used to prevent the growth of cancer cells within the body by stabilizing the cellular microtubules. This stabilization inhibits the tubular reorganization that occurs during cellular mitosis, preventing accumulation of cells at the injury site.[9] Paclitaxel is released from the stent during the 48 hours after deployment, followed with a slow release over the next 10 days.[9] Sirolimus (Rapamune) is a natural macro-

lide antibiotic and immunosuppressive agent, initially used to prevent transplant rejection.[11] Sirolimus stops cell-cycle progression by inhibiting DNA synthesis. This reduces intimal hyperplasia. Peak drug concentration occurs 4 hours after deployment, with approximately 50% of the total drug eliminated within the first 10 days and 90% of the remaining drug removed by 60 days.[9] Research is continuing on several other drugs within all categories.

The incidence of in-stent restenosis is reported to be significantly less using a DES. A meta-analysis on six randomized clinical trials on 3,669 patients comparing TAXUS and CYPHER stents reported angiographic restenosis rates to be 13.1% and 9.3%, respectively.[12] There are other issues that should be considered when using a DES. The cost of a DES is approximately $3,000, which is considerably higher than a BMS that costs $1,500. This has a significant impact on the cardiac catheterization laboratory budget. Elective coronary stenting, according to the randomized Stent Restenosis Study trial, increased total 1-year medical care costs by approximately $800 per patient, compared with conventional angioplasty.[8]

Medtronic Octopus suction stabilizer in off-pump CABG

Stent thrombosis is a catastrophic complication with a mortality rate reported up to 26%, occurring in the first days to weeks after stent implantation.[4] To prevent this complication, aspirin plus a thienopyridine (most commonly clopidogrel) is prescribed for a specified time. Currently, this treatment regime is recommended for 3 to 6 months if the patient has a DES, compared to 4 weeks if a BMS.[4] The cost of this medication may place an economic burden on the patient.

In September 2006, the FDA issued a statement related to coronary DES. The FDA held a public panel meeting of outside scientific experts in December 2006 to review all data from two recent research studies that found a small but significant increase in the rate of myocardial infarction and death possibly related to thrombosis in patients who received DES. The panel stated that concerns about thrombosis do not outweigh the benefits of DES as compared to bare metal stents, when used according to FDA-approved indications. The panel also recommended longer premarket clinical trials of DES with increased sample size and longer postapproval studies using uniform definitions of stent thrombosis and close evaluation of patient compliance with antiplatelet therapy.[13]

Other new technologies undergoing evaluation for treatment of CAD include various types of stents, such as biodegradable, low-speed rotators, and transluminal extraction catheters. Laser angioplasty was initially greeted with enthusiasm; however, the current consensus is that its use will be limited.

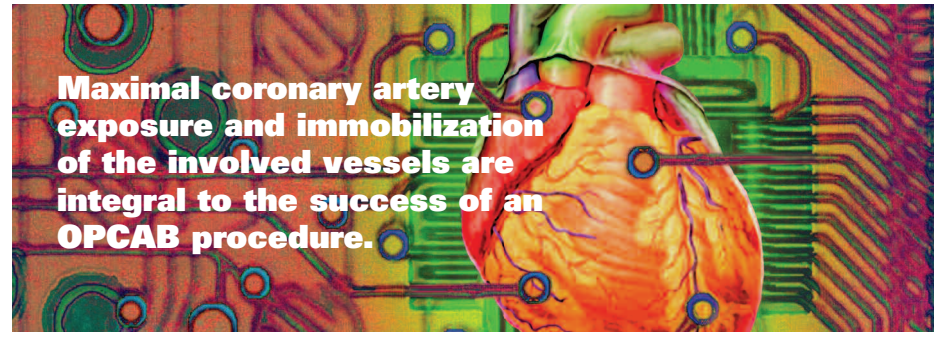
Off-pump CABG

Surgical intervention in CAD remains a treatment foundation despite PCI advances. In 2003, an estimated 467,000 CABG surgeries were performed on 268,000 patients.[1] Off-pump coronary artery bypass (OPCAB) denotes performing open-heart surgery, specifically CABG, without the use of cardiopulmonary bypass (aka the heart-lung machine). Vineberg performed the first OPCAB surgery in 1946 when implanting an internal mammary artery into myocardial muscle to improve ischemia.[14] To provide a

motionless, as well as bloodless, field for coronary grafting to occur, the cardiopulmonary bypass (CPB) machine was developed. Gibbon performed the first successful open-heart surgery utilizing cardiopulmonary bypass in 1953.[15] Improvements in CPB during the 1960s provided surgeons with a bloodless and motionless field through cardioplegic arrest to safely operate and maintain a high degree of graft patency. Coronary artery bypass grafting with the use of CPB continued basically unchanged for the next 20 years despite reports by several investigators on their OPCAB experiences.[15]

Potential physiologic derangements from CPB include a systemic inflammatory response that may alter coagulation resulting in bleeding, transiently impair postoperative ventricular function, and decrease plasma oncotic pressures causing interstitial fluid shifts and edema.[16] Additional complications from CPB may include air embolism, aortic dissection, stroke, and pulmonary dysfunction.[17] Consequently, in the late 1980s there was a resurgence of interest in OPCAB surgical techniques. Initial attempts in OPCAB focused on minimizing incision size and location through various small thoracotomy incisions. This was known as minimally invasive direct coronary artery bypass (MIDCAB), which means a standard median sternotomy approach wasn't used. The MIDCAB technique limited the surgeon to single- or double-vessel coronary revascularization and reduced operative field visibility. The standard sternotomy approach is most frequently used for multivessel OPCAB, although alternative incisional techniques may be employed.[18]

Maximal coronary artery exposure and immobilization of the involved vessels are integral to the success of an OPCAB procedure. Pericardial traction sutures or an apical suction device allow for targeted vessel display.[18] Early immobilization options included pharmacologic interventions such as esmolol or adenosine to induce a controlled bradycardia/transient ventricular asystole, in addition to various mechanical methods such as compression suture loops or soft tissue clamps to provide a motionless field.[19] Today, immobilization may be achieved by either a dual-pronged compression-type or suction-type stabilizer device. A compression stabilizer has a textured surface in each prong to avoid movement. It is positioned parallel to and spanning the vessel, and immobilizes the targeted area by pressure.[18] Mechanical stabilizer devices include the Octopus stabilizer by Medtronic, Inc., the Genzyme Immobilizer, and the Guidant Ultima II. A suction stabilizer device has rows of suction cups in each prong. (See Medtronic Octopus Suction stabilizer in off-pump CABG.) Immobility is achieved for the anastomosis by creation of a vacuum between the epicardial surface and the stabilizer arm.[16] (See Off-pump CABG Medtronic Octopus suction stabilizer on the heart.)

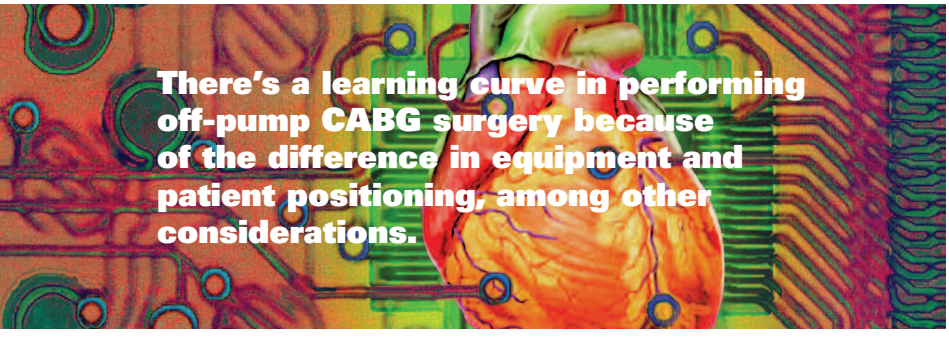


Debate exists regarding whether OPCAB is superior to conventional CABG surgery using cardiopulmonary bypass. Experts studied 200 patients randomized to on-pump or off-pump CABG, the number of grafts, graft patency rates, mortality, reoperation and postoperative complications were similar in both groups.[20] The OPCAB patients required less transfusions, had a lower creatinine kinase-MB and troponin I levels, and had a shorter postoperative length of stay (by one day) compared to the conventional CABG patients. The OPCAB graft patency rates at 3 months were lower (88%) compared to the on-pump CABG (98%) in a different study of 103 patients.[21] This study has been questioned by other researchers because of the apparent lack of OPCAB experience by the study surgeons.[22]

Researchers also retrospectively examined 2,273 OPCAB and 3,487 on-pump CABG patients who required the surgery on an urgent basis.[23] The OPCAB patients had a shorter length of stay and a lower rate of reoperation for bleeding compared to the on-pump patients.[23] A decrease

in postoperative cognition has been reported in both conventional and OPCAB patients and has been felt to be owing to multiple factors in the cerebral microcirculation.[24] In the on-pump patients, a decrease in postoperative cognition may result from embolization from an atherosclerotic or calcified aorta from the aortic cross-clamp and aortic cannulation.[18]

A study of 54 patients found that increased age and postoperative atrial fibrillation were associated with a decrease in postoperative cognitive function in OPCAB patients.[25] Other experts reported an improvement in cognition after CABG, however, a comparison of off-pump versus on-pump was not done.[26]



There's a learning curve in performing off-pump CABG surgery because of the difference in equipment and patient positioning, among other considerations. The operator experience in OPCAB is a significant factor contributing to a patient's outcome. Further studies examining both off-pump and on-pump CABG surgery are needed by surgeons skilled in both techniques.

Minimally invasive valve surgery

Valvular heart disease (VHD) is a malfunction of one or more of the four cardiac valves. The malfunction may be from stenosis, a narrowing of the valve lumen resulting in a decrease in forward blood flow or regurgitation (blood leaking back out of a closed valve), or both.[27] In the United States, VHD is far less common than CAD. A population-based study projected the national prevalence of valve disease at 2% to 5%.[28] Researchers reported the highest frequency of VHD in the 75 years of age or older group at a calculated prevalence of 11.7%, with mitral and aortic valve dysfunction predominating.[28]

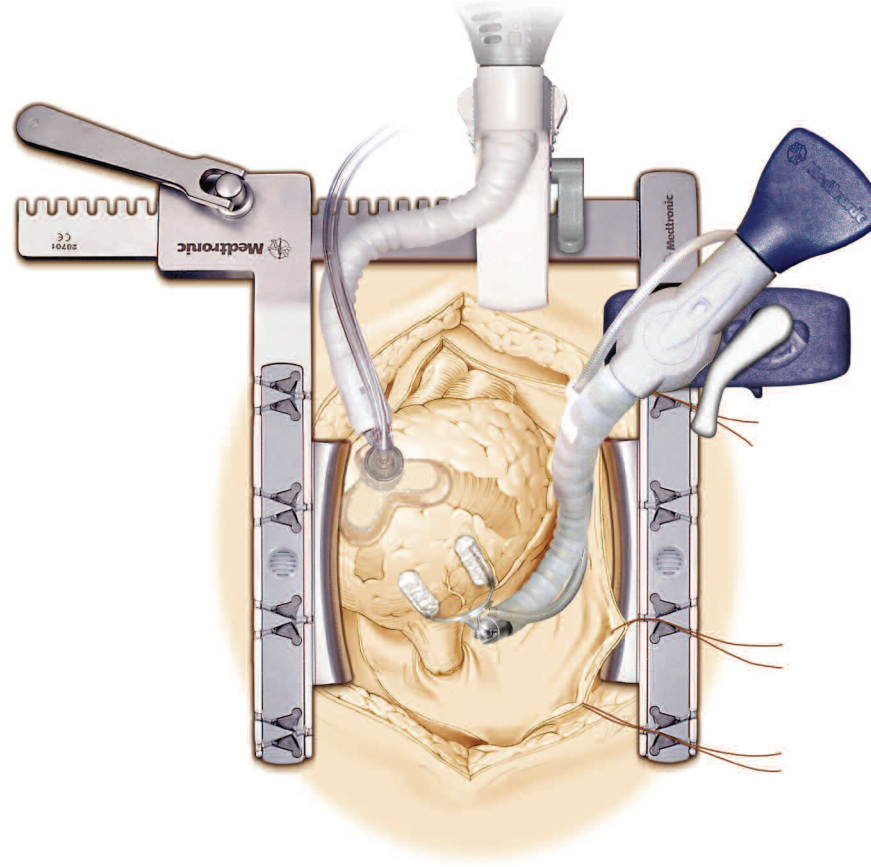
The mortality rates for valve surgery are higher than CABG. The Society for Thoracic Surgeons National Adult Cardiac Surgery Database published unadjusted mortality ranges of 5% to 6.4%, 3% to 4%, and 2.2% to 3.2% respectively for mitral valve replacement (MVR), aortic valve replacement (AVR), and coronary artery bypass grafting from 1996 through 2005.[29] If a combination procedure is performed, particularly an MVR and CABG, the mortality rate may exceed 11%.[29] A method to reduce the mortality rate may be through performing minimally invasive heart valve surgery (MIHVS).

Conventional heart valve repair or replacement necessitates a median sternotomy along with cannulation of the aorta and right atrium or vena cava for cardiopulmonary bypass.[27] This prolongs recovery along with postoperative length of stay, and increases the risk of complications, especially in the elderly patient. The first attempts to minimize conventional valve operations were through modifications in the median sternotomy incision, similar to those attempted in the MIDCAB procedure. These incisions may include a ministernotomy, parasternal, minithoracotomy, or a combination. The term "minimally invasive," when referring to valve surgery, is actually describing the size of the incision(s).[30]

The introduction of video-assisted technology in 1996 through multiple key hole incisions further reduced the invasive aspect of heart valve surgery.[30] Known as the Port-Access technique, it uses the femoral artery and vein as access for cardiopulmonary bypass (CPB). The venous return line of the CPB circuit is advanced into the right atrium. The femoral arterial return cannula is Y-shaped, with one limb used for blood return and the second limb used for deploying an endovascular balloon aortic clamp and infusing cardioplegia solution. The endovascular balloon clamp replaces the standard aortic cross-clamp used in a conventional on-pump procedure.[31] A catheter placed in the coronary sinus administers additional cardioplegic solution. The CPB machine connections are modified to accept this cannulation variation. Incisions in a valve Port-Access procedure typically include a mini thoracotomy

or modification of the standard sternotomy, along with a port incision for video access. Originally intended for both CABG and valve surgeries, Port-Access found increased use in the heart valve surgery population, both aortic and mitral.[30] Early results were conflicting. Experts reviewed 51 patients who had undergone mitral valve repair or replacement using a Port-Access device. Morbidity was high, with two patients having an aortic dissection and three patients requiring reoperation for valvular leakage.[31] However, other researchers found that patient-related factors such as age, surgery involving the mitral valve, and reoperation were predictors of outcome.[32] The short-term mortality in Glower's study was reported at 3.8%. Cardiovascular surgeons, anesthesiologists, and surgical teams require specialized training in insertion of the cannulas, endovascular balloons, and use of the video equipment when performing Port-Access surgery. Hospitals are required to purchase the video system with the associated disposable soft goods. Today, the Port-Access technique remains an option for minimally invasive valve surgery, either as a stand-alone procedure or in combination with others.

Off-pump CABG Medtronic Octopus suction stabilizer on the heart



Robotic valve surgery

Robot-assisted heart valve surgery allows the surgeon to operate from a console when performing surgery. In 1997, the voice-activated camera robot known as the Automated Endoscopic System for Optimal Positioning, or AESOP 3000 (Computer Motion Inc., Santa Barbara, CA) was used. The robotic arm is voice-controlled, allowing a hands-free operation of the camera.[33] The surgeon directly performs all other aspects of the surgery: cannula insertion, incisions, and so forth. The da Vinci Surgical System (Intuitive Surgical, Inc., Mountain View, CA) is composed of three components: a surgeon console, an instrument cart, and a visioning platform.[34] The operative console is removed physically from the patient, allowing the surgeon to sit comfortably with the head positioned to allow for a three-dimensional view. The finger and wrist movements of the surgeon are registered through sensors in computer memory banks, and these actions are transferred to an instrument cart that directly operates the instruments.[34] An assistant remains at the patient's side during the procedure. Robotic valve surgery is primarily performed on patients requiring mitral valve repair.[34] Cardiopulmonary bypass is achieved through femoral cannulation. In a mitral valve repair, a small lateral thoracotomy incision in the fourth intercostal space (ICS) is the working incision. The robotic camera is positioned in the working incision or

in a separate port. Two robotic instruments are placed in additional incisions in the fourth or fifth ICS along with the second ICS.[34] The aorta is clamped either transthoracically or by an endoaortic balloon similar to Port-Access. Catheters and instruments are manipulated by the surgeon at the console with the instruments precisely following this direction eliminating potential distractions (such as hand tremors or dropped instruments).[34] Study outcomes on this technique are encouraging. Researchers reported on 25 patients having a mitral valve repair using the da Vinci system over 1 year.[35] Twenty-one of these patients were extubated in the operating room, with a mean postoperative stay of 2.7 days. There were no mortalities or reoperations.

In a study between 25 patients undergoing robotic mitral valve repair compared to 39 patients with a conventional sternotomy repair, experts noted that cross-clamp and bypass times were longer in the robotic group.[36] However, blood use was significantly lower in the robotic group (2.8 units) compared to the conventional sternotomy (5.0 units).[36] The postoperative length of stay was shorter in the robotic (7.1 days) compared to the conventional (10.6 days). As with Port-Access and off-pump CABG techniques, a learning curve for the surgeon and staff in performing this technology exists that may temporarily cause an increase in patient complications. The economic burden to the hospital is considerable. A robotic system costs approximately one million dollars.[33] This doesn't include upgrades or additional robotic arms. Investigational techniques include performing valve surgery on a beating heart using a retrograde oxygenated coronary sinus perfusion.[37] Pilot feasibility trials are being conducted on percutaneous aortic valve replacement.[38]

Lessons learned

Technology is rapidly expanding the available treatment options in cardiovascular disease. The justification for using this technology should include a thorough review of potential risks versus benefits, including an analysis of physician commitment, the institution's procedure volumes, and financial impact including reimbursement. Further research is needed, particularly in examining the long-term outcomes of these techniques. ❖

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