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from coronary arteries as a prelude to angioplasty/stenting. There are two main types of coronary stent—‘bare metal’ and ‘drug eluting’. The latter contain a drug (e.g. sirolimus, paclitaxel, and others) that inhibits smooth muscle proliferation and thereby considerably re- duces the risk of restenosis, which is the most common complication

section 16 Cardiovascular disorders 3656 of stenting. Restenosis typically presents as exertional angina at 1 to 6 months following intervention: if it is not present at 6 months, it is unlikely to occur. Stents with bioresorbable scaffolds are now available, but concern regarding late stent thrombosis has limited their use. Treatment of valvular and other diseases Percutaneous techniques can also be used to treat some forms of valvular disease and close cardiac defects in (highly) selected cases. Balloon valvuloplasty is the preferred treatment, when feasible, for patients with stenosis of mitral and pulmonic valves. Transcatheter aortic valve implantation has proven safe and effective as an alterna- tive to surgical valve replacement in patients for whom surgical risk is prohibitive, and recent trials have supported use in patients with inter- mediate surgical risk. Valve-in-valve transcatheter replacement is now an option for some patients with degenerated surgically implanted bioprosthetic valves. Percutaneous clipping of mitral valve leaflets has been accomplished in some patients with mitral regurgitation, with safety equivalent to that of surgical treatment but less benefit. Atrial septal defect and patent foramen ovale can be closed with a percutaneously delivered clamshell device, with randomized trials showing that patients having cryptogenic stroke and patent foramen ovale are less likely to sustain recurrent stroke when the defect is closed compared to long-term anticoagulant or antiplatelet therapy. Occlusion of the left atrial appendage with a percutaneously delivered disc reduces the risk of embolic stroke in patients with atrial fibrillation and is an alternative to long-term anticoagulation for some patients. Introduction The birth of interventional vascular medicine is generally cred- ited to Charles Dotter, a radiologist from Portland, Oregon, who in 1964 first dared to relieve atherosclerotic stenosis of a patient’s femoral artery by passage of a percutaneously introduced dilator. Although Dr Dotter had a few notable successes, which were widely publicized in the lay press, the scientific community scorned him. His radical concept lay dormant until a decade later when Andreas Gruentzig, a young German radiologist studying in Zurich, revived it. Dr Gruentzig was convinced that percutaneous dilatation of ath- erosclerotic stenosis was a sound concept and proposed that Dotter’s solid dilator be replaced by a catheter with an inflatable cylindrical balloon at its tip. Using catheters he created in his own kitchen, he proceeded carefully and logically in applying his technique first to animal models, then to human peripheral vessels, and finally in 1977 to his ultimate goal, the human coronary artery. News of Gruentzig’s percutaneous transluminal coronary angioplasty (PTCA) was quickly embraced by the medical community, and the era of percu- taneous coronary intervention (PCI) was born. This chapter deals with percutaneous approaches to treating coronary, valvular, and congenital heart disease. Percutaneous coronary intervention PCI is the current general term applied to a variety of percutaneous catheter-based procedures that accomplish revascularization by either angioplasty (enlargement of a vessel lumen by modification of plaque structure), stenting (deployment of an internal armature or stent), atherectomy (removal or ablation of plaque), or thromb- ectomy (removal of thrombus). Several different devices have been developed to perform these procedures. The interventional cardi- ologist chooses among these approaches to best suit the particular requirements of each individual patient. Indications The indications for percutaneous revascularization have expanded dramatically during the past 40 years. In the early days of PTCA it was indicated for subtotal proximal occlusions of single vessels in patients with chronic stable angina pectoris who had failed medical therapy. As

experience grew and equipment improved, patients with unstable angina, total occlusions, bypass grafts, multivessel disease, and acute myocardial infarction were added to the list. Currently, the most common single indication for PCI is acute coronary syn- drome (see Chapter 16.13.4). PCI has traditionally been performed only in hospitals having cardiac surgical backup. However, as the procedure has become safer and the need for emergency bypass surgery less frequent (cur- rently <1% of all cases), it has become more common, particularly in Europe, for these procedures to be performed in facilities where surgical backup is not on site. Likewise, all patients undergoing PCI were once required to be potential candidates for bypass surgery in case of failure of the percutaneous procedure. Now some patients who are poor surgical candidates may undergo salvage interven- tion as their best or only avenue for revascularization. The choice of initial treatment (pharmacological, interventional, or surgical) for patients with each of the aforementioned coronary syndromes has been guided by evidence from several randomized clinical trials and is treated in more detail in the later section headed ‘Outcomes’. Devices and techniques Balloon angioplasty Balloon angioplasty is the traditional, basic technique of coronary intervention, although it is now uncommonly employed as a stand- alone treatment. Nevertheless, it is fundamental to the deployment of coronary stents, which are currently the most widely utilized of the interventional devices. The equipment for angioplasty is shown in Fig. 16.13.5.1 and consists of a coaxial array of guiding catheter, balloon catheter, and steerable guide wire. The procedure is accom- plished by first engaging the left or right coronary orifice with the tip of the guiding catheter to access the vessel containing the target lesion and to provide backup support during advancement of the guide wire and balloon across the lesion (Fig. 16.13.5.2a). Next, the guide wire is advanced through the guide catheter into the ap- propriate vessel and across the lesion to be treated. Typical guide wires are 0.014 of an inch in diameter (c.0.36 mm) and have a flex- ible spiral coil tip that can be directed by rotating their proximal end outside the body. The balloon catheter is then advanced over the guide wire until the deflated balloon lies across the target lesion. Finally, the balloon is inflated with a solution of dilute contrast me- dium to a pressure sufficient to expand the cylindrical balloon to its nominal manufactured diameter (Fig. 16.13.5.2b). The balloon size is selected to match the estimated diameter of the nearest seg- ment of normal vessel and the length of the target lesion. Sometimes

 intravascular ultrasound is used to assist in this choice. The balloon is then withdrawn and the result assessed by angiography and, occa- sionally, by ultrasound (Fig. 16.13.5.2c). Traditional angioplasty now finds its chief application in de- ployment of balloon-expandable stents. However, angioplasty may serve as a stand-alone interventional technique for the treatment of lesions of small vessels (<2.5 mm in diameter) and lesions lo- cated far distally or beyond tortuous segments where more rigid devices such as stents cannot reach. In experienced hands, with appropriate case selection, the initial success rate of balloon angio- plasty should exceed 95%. Abrupt closure of the vessel might be expected in about 3% of cases (usually due to dissection), but most of these can be corrected by deployment of a stent, resulting in a need for emergency bypass surgery in less than 1% of cases. The clinical consequence of vessel closure is often insufficient to justify surgery in vessels too small or distal for grafting. The technology of guide, balloon, and guide wire systems has ad- vanced to the point where few locations in the coronary anatomy are inaccessible. Totally occluded vessels can usually be success- fully crossed with appropriate manipulation of the right guide wire, enabling successful angioplasty. The success rate for angioplasty of totally occluded vessels depends upon the age, length, and com- position (thrombus vs. plaque) of the occlusion; it is well

over 90% in cases of acute thrombotic occlusion, and over 50% in cases of chronic occlusion (>3 months). The chief disadvantage of balloon angioplasty is the phenomenon of restenosis, which is discussed in more detail later in this chapter, and which spurred the development of newer devices in the hope of preventing restenosis. Cutting balloon The cutting balloon has several tiny longitudinally mounted blades that become erect when the balloon is inflated and create linear cuts along the vessel wall. This was conceived as a method to dilate a vessel less traumatically and thereby reduce the likelihood of resten- osis. This goal was never realized for de novo lesions, but the device has been advantageous for treatment of recurrent stenosis within previously deployed stents (in-stent restenosis) and for dilating le- sions located at the ostium of a vessel, which are otherwise often subject to elastic recoil when dilated. Stenting Bare metal stents Stenting has become the intervention of choice in about 90% of cases undergoing PCI. A modern-day vascular stent is actually an arma- ture, or internal skeleton, for restoring and maintaining the cylin- drical structure of the diseased vessel. Most stents are made from a thin-walled stainless steel or cobalt–chromium steel tube in which slots have been carved. The slotted tube is then mounted securely on a deflated angioplasty balloon and deployed at the target lesion of the coronary artery by inflating the balloon at high pressure with dilute contrast medium. When the balloon is deflated the stent re- mains expanded against the vessel wall, its slots stretched into diamond-shaped apertures (Fig. 16.13.5.3). Approximately 20% of the vessel wall is covered by metal, the remainder being an intrastrut aperture. This accounts for the surprisingly high patency of side Steerable guide wire Balloon Lesion Dilating catheter Guiding catheter Proximal pressure and injection Fig. 16.13.5.1 Balloon angioplasty. The guiding catheter gives access to the coronary artery and provides a platform against which the dilating apparatus can be advanced. The steerable guide wire is passed down the vessel being treated and provides a rail over which the balloon catheter can be advanced. Once centred on the atherosclerotic lesion, the balloon is inflated under pressure to dilate the narrowed segment of artery. Balloon catheter entering blockage (a) Inflated balloon stretching blockage (b) Re-opened artery after inflation (c)
Fig. 16.13.5.2 A typical lesion (a) before, (b) during, and (c) after balloon angioplasty.

section 16 Cardiovascular disorders 3658 branches following stent deployment, and the ability to access these side branches when necessary for further intervention. A variation of the slotted-tube stent is a balloon-deployed coiled wire (Wallstent and others). A coiled wire made from nitinol, or another alloy with shape-retaining characteristics, is compressed into a tubular delivery sheath, which is advanced over a guide wire across the target lesion. Once in its proper position the sheath is drawn back, allowing the stent to expand to its original size and shape (Fig. 16.13.5.4). As with slotted-tube stents, pre-or post- deployment dilation with a balloon may be necessary, depending upon the nature of the lesion treated and the device used. Although one of the original stent designs, the self-expanding stent is now used less commonly for coronary artery applications, but it still finds use in many peripheral vascular cases. Most current stent de- signs are hybrids, which incorporate desirable properties of both the slotted-tube and coiled-wire designs. Stents have gained remarkable popularity, mainly for three reasons. (1) Immediate complications are reduced because abrupt closure of the vessel due to dissection is less likely, emphasized by the fact that a stent is the best treatment for a balloon-induced dis- section. (2) The immediate result is better in terms of the diameter and smoothness of the lumen, which turns out to be of more than cosmetic value because the early gain in lumen size relates directly to the late outcome. (3) Stents have been demonstrated in random- ized clinical trials to be effective in reducing the likelihood of late restenosis. However, stents do have some disadvantages, which include the fact that they cannot

be deployed under some circumstances, their propensity to subacute thrombosis, and the persistence of some degree of restenosis (depending upon the size of the vessel and length of the lesion). Subacute thrombosis, a complication unique to stents, usually occurs within a few weeks after stent deployment. By contrast to restenosis, which is a gradual phenomenon, stent thrombosis is usually sudden, presenting as acute myocardial in- farction and requiring emergency revascularization, usually by bal- loon angioplasty. The likelihood of subacute thrombosis has been reduced to less than 1% by dual antiplatelet therapy with a com- bination of aspirin plus a thienopyridine (clopidogrel, prasugrel, ticagrelor, or ticlopidine). (a) (b) (c) Fig. 16.13.5.3 A balloon-deployed coronary artery stent before (a), during (b), and after (c) deployment. With permission from Maisel WH, Laskey WK (2007). Drug eluting stents. Circulation, 115, e426–7. Fig. 16.13.5.4 A self-deploying coil stent. The stent unfurls as its delivery (containment) sheath is pulled back. Image provided courtesy of Boston Scientific.

16.13.5 Percutaneous interventional cardiac procedures 3659 Drug-eluting stents The development of stents that gradually elute a drug into the sur- rounding vessel wall has reduced the need for repeat intervention due to restenosis from approximately 15% for bare metal stents to less than 5%. This technology is largely responsible for the rapid and sustained growth in popularity of stent procedures, such that most patients requiring coronary revascularization are now treated by percutaneous rather than surgical techniques. The design of the drug-eluting stent incorporates a polymer matrix coating that con- tains a drug which inhibits the proliferation of smooth muscle cells in the surrounding vessel wall. The active drug slowly elutes from this coating into the underlying tissue while the vascular response to injury caused by vessel dilation is most active. Drug elution is usu- ally complete by 2 months after stent deployment, but by modulating the proliferation of smooth muscle cells the growth of neointima covering the stent struts is limited, reducing the likelihood of resten- osis of the treated vessel. The first two types of drug-eluting stents to be commercially available use sirolimus and paclitaxel as the active drug. These drugs inhibit cell proliferation through different mechanisms, but have proven to be equally effective. Other drugs currently available in- clude everolimus and zotarolimus. Although excessive neointimal growth is undesirable, some is needed in order to cover the stent struts and prevent thrombosis. Dual antiplatelet drug therapy is necessary to minimize this risk as long as the struts are exposed. Bare metal stents are usually fully covered by 2 months, but drug- eluting stents may remain uncovered for 6 months or longer. For this reason, most cardiologists recommend that dual antiplatelet therapy be continued along with aspirin for at least 1 year following deploy- ment of drug-eluting stents. Bioresorbable stents The concept of a stent which is gradually absorbed or degraded is attractive for several reasons. The metal stent scaffold is no longer needed after the vessel has healed from the trauma of dilation and implantation. The very presence of a metal scaffold and/or its polymer matrix coating may promote inflammation, leading to lumen loss after the antiproliferative drug has been delivered, and thrombosis may occur if tissue coverage of metal struts is incom- plete. The metal scaffold also limits normal vascular motion as well as imaging by CT or MRI. In other words, the ideal coronary artery stent would disappear after it is no longer needed, which has driven the development bioresorbable stents. Two main types of bioresorbable stents are now available: one with a bioresorbable matrix applied to a conventional metal stent scaffold, and another in which the entire stent scaffold is nonmetallic and absorbable. Two absorbable matrix stents studied in random- ized trials are the everolimus-eluting Synergy (Boston Scientific) and biolumis eluting Nobori (Terumo), both of which are available for clinical use in

Europe, and the Synergy stent has been available in the United States since 2015. They have comparable outcomes com- pared with conventional drug-eluting stents in multiple studies, and a meta-analysis of four different randomized trials suggests reduced incidence of very late (four years follow-up) stent thrombosis. The Absorb (Abbott Vascular Corporation) and DESolve (Elixir Medical Corporation) stents deliver everolimus and novolimus re- spectively from a totally absorbable polymer scaffold. DESolve is available for clinical use in Europe, and Absorb has been FDA ap- proved in the United States since 2016. They are bulkier than equiva- lent metal devices and are prone to fracture, hence vessel sizing and proper stent deployment are critical. Although randomized trials show clinical outcomes that are noninferior to those of conventional drug-eluting stents, several randomized trials—including the most recent ABSORB III trial—indicate that the incidence of stent throm- bosis is twice that of conventional drug-eluting stents. The AIDA trial comparing bioresorbable scaffolds with metallic stents in rou- tine percutaneous coronary intervention showed definite or prob- able device thrombosis at two years to be 3.5 versus 0.9% for the two groups respectively. Many cardiologists are therefore awaiting further evidence of benefit before embracing this enticing but ex- pensive technology. Atherectomy Rotational ablation Rotational ablation (Rotablator) is a method of pulverizing plaque into particles smaller than the size of a capillary, which wash away with the circulating blood. This process is accomplished by means of a diamond-studded burr, which rotates at approximately 150 000 rev/min (Fig. 16.13.5.5) and is advanced along a guide wire into the plaque. The diamond studs on the forward face of the olive-shaped burr selectively cut into hard substances such as plaque and cal- cium, sparing the soft surface of normal tissue. During rotational atherectomy a vasodilating solution is infused into the artery prox- imal to the burr to prevent spasm and to maintain maximal coronary flow, which carries away particulate debris. Burrs are manufactured in sizes ranging from 1.5 mm to 2.5 mm in diameter. Atherectomy often requires the use of two or three burrs of progressively larger size until an adequate lumen size is achieved. Although occasion- ally used as a stand-alone procedure, rotational ablation is usually employed to ‘debulk’ lesions prior to final dilatation with a balloon or stent. Rotational ablation was originally conceived as a potential solu- tion to the problem of postintervention restenosis. Unfortunately, it has failed to outperform balloon angioplasty in this regard and has assumed the role of a ‘niche’ device for special situations. It is most commonly used in the treatment of heavily calcified lesions that do not respond well to balloons and stents. It is also useful in treating diffuse, osteal, and bifurcating lesions. The frequency with which ro- tational ablation is employed varies by operator, but averages less than 5% of most centres’ cases. It has the disadvantages of being an expensive addition to other interventional modalities, is unable to adequately increase the lumen of large vessels, and is contraindi- cated in lesions containing thrombus. Due to its tendency to tran- siently decrease contractility during the ablation process, it is also Fig. 16.13.5.5 Rotational atherectomy. The rotating burr pulverizes plaque as it is advanced over the guide wire into the lesion.

 relatively contraindicated in patients whose left ventricular function is severely impaired. Directional coronary atherectomy Directional coronary atherectomy (DCA) is achieved with a device illustrated in Fig. 16.13.5.6 that utilizes a rotating cylindrical blade which is advanced across an open aperture near the tip of a cone- shaped catheter directed by a guide wire. Opposite the aperture is an eccentric balloon, which when inflated compresses plaque of the opposite vessel wall into the aperture, where it is cut away by the rotating blade and pushed into the nose cone. The direction of the aperture can be rotated so that slices of plaque are removed in a ra- dial fashion by multiple cuts taken at different locations

around the circumference of the vessel. The catheter can then be withdrawn and the excised plaque removed from the nose cone. The catheter may be reintroduced, if necessary, for more atherectomy. Although DCA was originally devised with the hope of reducing the incidence of restenosis, it has failed to outperform balloon angio- plasty in most circumstances. It has therefore assumed the role of a ‘niche’ technology, which is useful in particular situations such as very eccentric proximal lesions, and lesions involving the ostia of major side branches. Removal of plaque at branch points seems to reduce the likelihood of plaque shifting from one branch to another as the respective lesions are dilated with balloons or stents. However, DCA has the disadvantage of requiring a rather large, stiff device, limiting its application to proximal lesions of large vessels. Furthermore, the removal of plaque seems to have surprisingly little effect on restenosis. DCA is currently employed in less than 5% of interventional cases. Other devices The transcutaneous excision catheter device was developed at about the same time as DCA. It employs a rotating conical blade that cuts away plaque and clot as it is advanced over a guide wire. The resulting debris is sucked back through the catheter into a reservoir outside the body. Although originally developed as an atherectomy device, it has found its chief application in treating clot-laden le- sions, but it has not gained wide usage. Excimer laser coronary atherectomy (ELCA) employs a fibre- optic catheter directed by a guide wire to deliver bursts of excimer laser energy to the plaque. Disintegrated plaque washes away in the circulation. However, ELCA has also failed to solve the restenosis problem and is used uncommonly in most centres, but remains the sole surviving member of a number of laser applications that have been tried and failed over the past 40 years. It finds its most fre- quent application in treatment of osteal lesions, stent restenosis, and diffuse calcified disease. Because of the limitations of fibre size it is usually followed by balloon or stent treatment. Thrombectomy Thrombectomy is an adjunct to angioplasty and stent procedures in patients with acute myocardial infarction and thrombus-laden le- sions. Its purpose is to prevent distal embolization by removing the thrombus prior to balloon dilation and stent deployment. The de- vices for achieving this have become simpler over time. The simplest and least expensive is called a Pronto, which is a catheter, delivered over a guide wire, that has a relatively large inner lumen attached to a suction syringe. As blood is withdrawn through the catheter, its tip is moved back and forth through the thrombus, picking it up and re- moving it. A more complex device called AngioJet uses the Venturi effect from a high-velocity jet of water, which draws thrombus into a window near the tip of a catheter directed by a guide wire and pro- pels it into a reservoir. Another device called the Excisor employs a helical screw at the end of a catheter, which breaks up the clot so that it can be withdrawn through the catheter. Both these devices currently find their chief application in the treatment of degenerated and clot-laden veingraft lesions. Although suction thrombectomy seems logical prior to crossing a thrombotic vessel occlusion in pa- tients with acute ST-elevation myocardial infarction recent studies show no benefit from its routine use in this situation. Distal protection Distal protection devices are methods of capturing and collecting thrombus and other debris that may embolize distally from the target lesion during the use of many of the interventional tools just mentioned. They may be particularly beneficial during the treatment of old, degenerated vein grafts in which distal embolization is espe- cially common. Two general approaches are employed. The simplest is a guide wire with a filter on its end (Filterwire, Fig. 16.13.5.7). The filter looks like a windsock and catches debris released proximal to it. The other approach (PercuSurge) is to use a guide wire with a balloon near its tip which is progressively inflated until it occludes the distal portion of the vessel being treated. Intervention is then performed over the guide wire proximal to the occlusion balloon. Once the intervention is complete an export catheter is advanced over the guide wire and any debris removed by suction. Finally, the

distal balloon is deflated, restoring flow, and the guide wire removed. Window Plaque (b) (d) Cutting element Atherocath (a) Balloon Nose cone (c) Fig. 16.13.5.6 Directional coronary atherectomy: (a) the catheter is inserted such that the blade housing is adjacent to the plaque to be removed. (b) The balloon on the opposite side of the blade housing is inflated, pushing the aperture over the plaque. (c) The rotating cylindrical blade is advanced across the window of the housing and cuts away plaque, packing it into the nose cone. (d) The catheter can be rotated to remove plaque elsewhere on the circumference of the vessel.

16.13.5 Percutaneous interventional cardiac procedures 3661 Brachytherapy The local, catheter-based delivery of β-or γ-radiation has been demonstrated to reduce the incidence of recurrent stent resten- osis. Radiation is delivered with the assistance of a radiation ther- apist after initial treatment of stent restenosis with a cutting balloon, Rotablator, or conventional balloon. The benefit of brachytherapy appears to be limited to treatment of stent restenosis and it is not re-commended following initial deployment of a stent. Brachytherapy also prolongs the period of risk for subacute thrombosis, making it necessary to treat patients with both aspirin and clopidogrel for at least 6 months after treatment. However, the need for brachytherapy has been virtually eliminated by drug-eluting stents. Not only is re- stenosis less likely after initial deployment of a drug-eluting stent, but restenosis—when it does occur—is most effectively treated by concentric deployment of a second drug-eluting stent. Selection and evaluation of treatment targets Fractional flow reserve In cases of acute myocardial infarction or single-vessel disease the identification of the treatment target (so-called ‘culprit lesion’) is usually straightforward. However, in patients having lesions of multiple vessels it is often unclear which vessels require treatment. Treating a lesion that is not responsible for causing ischaemia can create a problem where previously none existed. An unnecessary stent can still lead to restenosis and other complications, not to men- tion needless additional cost. On the other hand, failure to treat a vessel having borderline stenosis may overlook a source of ischaemia. Measurement of fractional flow reserve has proven to be a useful method of identifying the physiological significance of coronary ar- tery lesions, especially in vessels having lesions with borderline per- centage stenosis (50–70%). It is performed using a pressure wire to cross an area of disease in a coronary artery; the pressure drop across a lesion is measured at rest and during maximal dilatation with an adenosine infusion. Fractional flow reserve (FFR) is the quotient of the mean pressure on either side of a coronary stenosis during max- imum vasodilation. An FFR quotient of less than 0.75 correlates with stress-induced defects in myocardial perfusion imaging studies. Such a lesion is capable of causing ischaemia and merits treatment. The FFR therefore facilitates clinical decisions in the catheterization la- boratory. Well-designed studies have shown that use of this method to guide treatment results in improved clinical outcomes. Intravascular ultrasound Intravascular ultrasound (IVUS) is a useful adjunct to interven- tional coronary procedures. It is performed by passing a small cath- eter having a rotating ultrasound crystal at its tip down a guide wire positioned in a coronary artery. Tomographic cross-sectional images of the artery are produced as the crystal is withdrawn. These images enable precise measurement of the dimensions of the arterial lumen plus visualization of the arterial wall and any plaque that might be present. Minimum cross-sectional area of coronary artery stenosis measuring less than 4.0 mm2 indicates that the stenosis is severe enough to cause ischaemia and likely to need treatment. The most common application of IVUS is in measuring the diameter of normal artery adjacent to a lesion in order to choose a stent of ap- propriate size. IVUS is also very useful for assessing whether a stent has been adequately deployed. Optical coherence tomography Optical coherence tomography (OCT) is a method of creating cross- sectional images of the artery

similar to those produced by IVUS. The difference is that reflected light, rather than ultrasound, is used to create the images. The advantage of OCT is that its spatial reso- lution is 10 times greater than that of IVUS. However, the use of light requires that the artery be flushed with saline in order to clear blood from the imaging field. Although this can be achieved safely, it is cumbersome enough that OCT has not yet gained widespread use in clinical practice. Complications PCI exposes the patient to all the potential complications of cardiac catheterization presented in Chapter 16.3.4. In addition, it carries the risk of other complications unique to interventional procedures. Most of these stem from four general processes that cause adverse outcomes in coronary artery intervention: abrupt closure, distal embolization, stent thrombosis, and restenosis. Patient characteris- tics such as age, acute coronary syndrome, previous bypass surgery, and renal insufficiency are major determinants of risk. When con- sidering PCI for a patient, it is important to weigh the likelihood of these adverse outcomes against the expected chance of adverse events without intervention. The approximate frequencies of various specific complications from PCI are listed in Table 16.13.5.1. As in diagnostic catheterization, the likelihood of these complications also depends upon operator skill. Fig. 16.13.5.7 Distal protection device: FilterWire. Image provided courtesy of Boston Scientific. Table 16.13.5.1 Complications of percutaneous coronary intervention Complication Frequency (%)a Death 0.5–2 Acute myocardial infarction 2–5 Emergency bypass surgery 0.5–2 Abrupt closure 1–2 Subacute stent thrombosis <1 Peripheral arterial complications 5 Restenosis (clinical) 5–30 a These rates are approximate and vary widely with the clinical setting and patient characteristics. These are in addition to the usual complications of cardiac catheterization presented in Chapter 16.3.4.

 Abrupt closure and distal embolization Abrupt closure and distal embolization account for most of the im- mediate complications of PCI, especially acute myocardial infarc- tion and emergency coronary artery bypass surgery. Dissection, spasm, and thrombosis are the leading causes of abrupt closure. The availability of stents has reduced the need for emergency by- pass surgery to less than 1% because these are an effective treatment for acute dissection in most cases. Nevertheless, dissection some- times extends with the addition of each stent, and occasionally the stent itself can be the cause of dissection at one of its edges. Acute thrombosis may occur in spite of routine prophylactic treatment with anticoagulants (heparin, low molecular weight heparin, or bivalirudin) and aspirin: glycoprotein IIb/IIIa inhibitors may stop this process and are sometimes given prophylactically, especially in high-risk cases. Incomplete stent deployment seems to be a leading cause of thrombotic occlusion. Distal embolization is surprisingly uncommon, except when patients have acute coronary syndromes or visible thrombus. It is especially troublesome for patients with de- generated or thrombus-laden vein grafts. Embolization may result in discrete occlusion of branch vessels or the phenomenon called ‘no reflow’, which is manifest by reduced flow without identifiable occlusion and thought to be due to capillary plugging from showers of microemboli. Distal protection devices (Fig. 16.13.5.7) may help prevent these problems. Both abrupt closure and no reflow usually cause some degree of myocardial infarction, the likelihood of infarc- tion being a matter of how it is defined: non-ST-elevation infarction indicated only by a rise of troponin or creatine kinase enzymes is more common than ST-elevation (Q wave) infarction. Stent thrombosis Thrombosis is a serious complication of particular concern for stents. It rarely occurs after the first 24 h following isolated balloon angio- plasty or atherectomy. However, when a stent is deployed it may occur at a later time and is manifest by acute myocardial infarction. It is a medical emergency that must be

managed in a fashion similar to spontaneous acute infarction. Emergency reperfusion by balloon angioplasty is usually preferred, unless a catheterization laboratory is unavailable, in which case thrombolytic therapy is recommended. In the early days of stenting this complication occurred in over 3% of cases in spite of vigorous anticoagulation including intravenous heparin and warfarin, a treatment that required several days of hos- pital stay for the initiation of warfarin therapy and delayed the wide- spread acceptance of stenting. However, once the current treatment using oral antiplatelet agents was proven to be superior, the length of hospital stay and local bleeding complications were reduced, and the use of stents grew rapidly. Stent thrombosis now occurs in less than 1% of cases. Thrombosis is defined as subacute when it occurs between 1 day and 1 month following stent deployment. Subacute thrombosis is equally likely for bare metal and drug-eluting stents. Thrombosis occurring more than one month after stent deployment is called late stent thrombosis and is particularly associated with drug-eluting stents (both metallic and bioresorbable scaffolds). To minimize the risk of late stent thrombosis, dual antiplatelet therapy with aspirin and thienopyridine should be continued without inter- ruption for at least 6–12 months following implantation of drug- eluting stents, and perhaps even longer for those with bioresorbable scaffolds. Restenosis Restenosis was once the Achilles heel of coronary intervention. In patients undergoing isolated balloon angioplasty the likelihood of restenosis at 6 months following intervention lies between 30 and 50% if defined by angiographic criteria, and approximately 25% if defined by the clinical recurrence of symptoms. The use of bare metal stents reduced the angiographic rate of restenosis to about 25% and the clinical rate to as little as 10%. Drug-eluting stents have further reduced the rate to 5% or less, depending upon clinical and ana- tomic circumstances. The risk of restenosis varies according to indi- vidual factors such as vessel diameter and lesion length. Restenosis typically presents clinically as exertional angina at 1 to 6 months following intervention. Restenosis occurring more than six months after implantation is less likely, but still happens occasionally. As described earlier, it is caused by the proliferation and migration of smooth muscle cells into the lumen of the treated vessel, a process that can be significantly modulated by use of drug-eluting stents. Outcomes Chronic stable angina Randomized clinical trials have shown that patients with single- and double-vessel disease experience a more rapid and complete resolution of symptoms, and a greater improvement in treadmill exercise performance, when treated by balloon angioplasty rather than by pharmacological therapy for chronic stable angina pectoris. However, this comes at the price of a greater likelihood of repeat intervention or bypass surgery at 6 months, largely due to the need to treat restenosis. Nevertheless, the rate of bypass surgery becomes equal in both groups by 3 years. More recent studies employing drug-eluting and bare metal stents continue to support these find- ings. Therefore, medical therapy is an acceptable initial strategy for low-risk patients. Intervention is recommended for higher- risk patients and those not responding to medical therapy. When compared to coronary bypass surgery, PCI provides similar relief of symptoms and similar rates of mortality and myocardial infarc- tion at 5-year follow-up, with the exception of diabetic patients who have somewhat better 5-year survival rates when treated surgically. Otherwise, the main difference between patient groups randomly assigned to surgery or percutaneous intervention is that repeat cath- eterization or revascularization is less frequent for those having sur- gery. Again, this difference is largely due to the effect of restenosis and less complete revascularization in the interventional group. See Chapter 16.13.4 for further discussion. Unstable angina The choice between initial aggressive treatment (catheterization and revascularization) and initial conservative treatment (medical therapy with catheterization and revascularization only for those who have continued evidence of ischaemia) for patients with un- stable angina has been

controversial. However, recent studies favour an aggressive approach to these patients, especially those having high clinical risk or evidence of non-STEMI. See Chapter 16.13.4 for further discussion. Acute myocardial infarction Percutaneous intervention has been shown to be an effective treatment for acute myocardial infarction with ST-segment elevation

 (STEMI), both as a salvage procedure after failed thrombolytic therapy and as a direct initial approach to reperfusion. Randomized trials have shown that direct intervention for STEMI is superior to initial thrombolytic therapy when performed in centres with ex- pert interventionists and catheterization facilities that are available around the clock. Direct PCI is also an option for patients presenting outside these centres provided that they can be transferred and ef- fectively treated in less than 90 min. In any case, direct PCI is the treatment of choice for patients in whom thrombolytic therapy is contraindicated and for patients who are haemodynamically un- stable. See Chapter 16.13.4 for further discussion. Economic considerations The cost of equipment and supplies for percutaneous coronary procedures may become a limiting factor, particularly in developing countries and in healthcare systems with stringent budgets. Most catheters, guide wires, and other supplies are intended for onetime use. Expendable supplies alone cost approximately £750 ($US 1200) for a simple balloon angioplasty procedure. That cost may be multi- plied several-fold when drug-eluting stents are used—these are two to three times more costly than bare metal stents, although the added cost is offset somewhat by the reduced likelihood of repeat procedures necessitated by restenosis. The coverage of this add- itional cost varies considerably throughout the world, depending on insurance and government policies. Nevertheless, the cost of a single percutaneous revascularization procedure usually remains less than that of a comparable coronary bypass operation. However, when the added cost of repeat percutaneous revascularizations necessitated by restenosis is considered, the price difference between the two therapeutic approaches narrows. Noncardiac surgery in patients following coronary intervention An estimated 5–10% of patients undergo noncardiac surgery within 1 year following coronary stent implantation. When surgery is performed within 6 weeks of intervention there is a high risk of death or myocardial infarction usually secondary to stent thrombosis, this risk is highest in patients with drug-eluting stents. The risk continues to be significant for at least 6 months. In individual cases the risk is higher, for example where a major coronary artery is stented (left main stem or proximal left anterior descending artery). For this reason it is rea- sonable try to defer elective surgery for at least 6 months following stent implantation. Where urgent surgery is required then a delay of 6 weeks is advisable. Where possible dual antiplatelet therapy should be continued in those operated on within 6 months except where the risks of perioperative bleeding are unacceptable. Percutaneous treatment of valvular and structural disease Allain Cribier in France developed the treatment of valvular stenosis by means of balloon catheters in the 1980s. The clinical utility of the procedure depends on the valve treated and the age of the patient. Percutaneous aortic valve replacement is now an effective alterna- tive to surgery in patients having very high surgical risk. Catheter- deployed clips can reduce the severity of mitral regurgitation. Mitral stenosis Balloon valvuloplasty of the mitral valve has become the treat- ment of choice for selected patients with rheumatic mitral stenosis. The most common approach to the mitral valve is via trans-septal puncture of the left atrium from percutaneous access of the right femoral vein. After passing a stiff guide wire with a curved soft tip across the mitral valve, an appropriately sized balloon is centred on the valve and inflated with dilute contrast medium, tearing open the fused commissures and allowing the valve to open more nor- mally. A dumbbell-shaped balloon, named after Dr Inoue, is often utilized, preventing the

balloon from slipping off the valve during inflation (see Fig. 16.13.5.8). Clinical improvement, complications, and durability of the outcome from balloon mitral valvuloplasty have been shown to be comparable to surgical commissurotomy in appropriately selected patients. To be a candidate for balloon mitral valvuloplasty a patient must have no evidence of thrombus in the left atrium. Other features which auger poorly include im- mobility of the valve leaflets, severe calcification, thickening of the chordae tendineae, and more than mild regurgitation. Balloon mi- tral valvuloplasty is generally recommended as the procedure of first choice for patients with favourable anatomy. Mitral regurgitation Percutaneous treatment of mitral regurgitation is being approached by two different strategies. The first involves applying a clip to the mitral valve commissures, effectively creating a dual orifice valve. The second approach is to pass a ring into the coronary sinus which constricts the mitral valve annulus, enabling better coaptation of the valve leaflets. Experience is greatest with the clip device (MitraClip). The EVEREST II trial indicates that the severity of mitral regurgita- tion can be safely reduced in two-thirds of cases. An attractive aspect of this procedure is that its performance does not preclude surgical repair if subsequently needed. Survival in this randomized trial is similar at 4 years follow-up, but the likelihood of requiring surgery or repeat clipping is nearly 25% in the clip-treated group. Surgical repair of the mitral valve remains the preferred treatment for most patients with mitral regurgitation requiring treatment. Percutaneous treat- ment is an acceptable option for patients with severe primary mitral regurgitation for whom the risk of surgery is high due to comorbidity. Aortic stenosis Experience with balloon valvuloplasty for patients with aortic stenosis has been disappointing, largely due to an almost universal tendency for the stenosis to recur within 1 year. Consequently, it is performed as a stand-alone procedure only under unusual circumstances. It has a role for children with congenital aortic stenosis, where temporary treatment by valvuloplasty may allow the child to complete growth before requiring surgical valve replacement. It is now used to prepare the aortic valve in advance of transcatheter aortic valve implantation (TAVI). These valves are fashioned from bovine pericardium inside a cylindrical cage that is either balloon expandable (Edwards SAPIEN) or self-expanding (Medtronic CoreValve) (see Fig. 16.13.5.9). TAVI has been studied in a randomized trial comparing the SAPIEN per- cutaneous valve with medical therapy in patients whose surgical risk for valve replacement is prohibitively high (PARTNER Study, cohort B). Patients randomized to TAVI showed improved outcome at one year compared to patients assigned to medical therapy (mortality

 (a) (b) (c) (d) Fig. 16.13.5.8 Percutaneous balloon mitral valvuloplasty. (a) The distal portion of the balloon is inflated after passing through the intra-atrial septum and mitral valve. (b) The distal balloon is pulled back against the stenotic valve. (c) The proximal portion of the balloon is inflated, locking it across the valve. (d) The waist of the balloon is inflated, dilating the valve orifice. With permission from Nobuyoshi M, et al. (2009). Percutaneous balloon mitral valvuloplasty: A review. Circulation, 119, e211–e219. (a) (b) (c) Fig. 16.13.5.9 Current widely available transcatheter valves. (a) The Edwards SAPIEN THV balloon- expandable valve (Edwards Lifesciences, Irving California, USA) incorporates a stainless-steel frame, bovine pericardial leaflets, and a fabric sealing cuff. (b) The SAPIEN XT THV (Edwards Lifesciences) utilizes a cobalt chromium alloy frame and is compatible with lower profile delivery catheters. (c) The Medtronic CoreValve (Medtronic, Minneapolis, Minnesota, USA) incorporates a self-expandable frame, porcine pericardial leaflets, and a pericardial seal. Reprinted from J Am Coll Cardiol, vol. 60, Webb JG, Wood DA, Current status of transcatheter aortic valve replacement, pp. 483–92,

30.7% vs. 50.7%). Cohort A of this study randomized patients whose surgical risk was considered high, but not prohibitive. Mortality for patients receiving TAVI was less than surgically assigned patients at 1 month (3.45 vs. 6.5%), but similar at 1 year (24.3% vs. 26.8%) and 2 years (33.9 vs. 35.0). Symptom improvement was similar for both treatments. Risk of stroke was greater for TAVI at 1 month (5.5% vs. 2.4%), but not different by 1 and 2 years. As a result of this study TAVI became clinically available throughout the world in 2012. In 2016 the SAPIEN 3 and PARTNER 2 trials compared TAVI and surgical valve replacement in patients having intermediate surgical risk. Outcomes were statistically similar after two years' follow-up. The newest application of TAVI is treatment of failed bioprosthetic valves by valve-in-valve implantation. The Valve-in-Valve Inter national Data (VIVID) registry has demonstrated acceptable out- comes, including 83.2% one-year survival. Pulmonary stenosis Balloon valvuloplasty is the treatment of choice for patients with pulmonary stenosis. Most are children whose valves respond well to this treatment, the advantage of avoiding surgery outweighing the moderate tendency for restenosis of these valves. Percutaneous closure of cardiac defects Atrial septal defects and patent ductus arteriosus can be closed percutaneously with catheter-delivered devices. One such de- vice, called a clamshell (brand names include Amplatzer, Helex, and STARFlex), has been used for this purpose for some years (Fig. 16.13.5.10). It is now available throughout the world and is useful for closing smaller defects, although larger defects still require surgical closure. A concurrent nonrandomized trial com- paring outcome for percutaneous versus surgical closure of atrial septal defect suggests shorter hospital stay and fewer complica- tions for the percutaneous approach, which is now often preferred for patients with smaller ostium secundum type defects. Closure of patent foramen ovale (PFO) can be accomplished by devices similar to the clamshell used for atrial septal defect (Amplatz PFO Occluder, STARFlex, Gore Helix/Cardioform and others). Two randomized trials (CLOSE and Gore-REDUCE) showed statistically significant reduction of recurrent stroke for patients treated by closure rather than medical therapy alone. PFO closure has also been advocated for migraine sufferers, but the Migraine Intervention with STARFlex Technology (MIST) trial did not show significant reduction of the primary study endpoint, although the overall burden of migraine was re- duced, hence closure of PFO for prevention of migraine remains controversial. Percutaneous left atrial appendage occlusion In patients with atrial fibrillation the most common cause of stroke is embolic thrombus originating from the left atrial ap- pendage, and long-term anticoagulation is usually required. For patients who cannot tolerate anticoagulation a novel approach to stroke prevention is occlusion of the left atrial appendage with a device such as the Watchman pictured in Fig. 16.13.5.11. This de- vice seals off the source of most emboli and thereby reduces the risk of thrombotic stroke. Several devices are under development, but the Watchman has been most extensively studied and is the only such device approved for clinical use in the United States. The PROTECT AF trial published in 2013 compared patients ran- domized to Watchman implantation with those treated by conven- tional warfarin therapy. The primary endpoint (stroke, systemic embolism, and cardiovascular or unexplained death) occurred in 3 per 100 patient years for the Watchman group, compared to 4.9 for the warfarin group. However, procedural complications (includ ing 5% pericardial effusion) occurred in 8.7% of the Watchman group, leading to a subsequent study (PREVAIL) which dem- onstrated a more acceptable 4.2% procedural complication rate. Current guidelines recommend left atrial occlusion for patients with nonvalvular atrial fibrillation who are not good candidates

Fig. 16.13.5.10 Amplatzer septal occluder made of 0.005 inch (0.127 mm) Nitinol wire tightly woven into two round discs with a 4 mm connecting waist (arrowheads). Arrow indicates the negative microscrew adaptor mounted on the right atrial disc. Reprinted from J Am Coll Cardiol, vol. 31, Thanopoulos BD, Laskari CV, Tsaousis GS, Zarayelyan A, Vekiou A, Papadopoulos GS, Closure of

atrial septal defects with the Amplatzer occlusion device: preliminary results, pp. 1110–6, Copyright 1998, with permission from Elsevier. Fig. 16.13.5.11 Artist’s rendering of the Watchman device (Boston Scientific Corporation). The nitinol frame is covered with polyethylene and held in place by ten barbs. Image provided courtesy of Boston Scientific.

Revision #1
Created 2026-01-22 16:39:21 UTC by Omar Ayman
Updated 2026-01-22 16:39:21 UTC by Omar Ayman