Stents in medicine

Coronary artery stents

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Summary

The use of coronary stents to treat the acute complications of percutaneous transluminal coronary angioplasty and to reduce the re-stenosis rate following this procedure is reviewed.

Keywords: stents, coronary artery stenosis, percutaneous transluminal coronary angioplasty

Figure 1 The Palmaz–Schatz stent, one of the most commonly used stents in the UK, comes in different lengths (up to 16 mm). The unexpanded stents are shown on the left and these are mounted on standard angioplasty balloons. After dilatation, the stents remain expanded (right). The fine metallic struts of this stent are difficult to see even on modern digital fluoroscopy imaging systems

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Percutaneous transluminal coronary angioplasty (PTCA) is widely utilised to treat patients with angina pectoralis who are symptomatic despite medical therapy and in whom surgical revascularisation is inappropriate. Significant advances in PTCA technology and the introduction of new devices (eg, laser and arterectomy catheters) have failed to improve on the results of standard balloon PTCA. Coronary stents are used not only to treat acute complications during PTCA but also to reduce the re-stenosis rate after successful PTCA. Their clinical use is set to expand at an exponential rate.

Sigwart and colleagues first reported the use of coronary stents in patients in 1987 as bail-out procedures in a small number of patients with abrupt vessel closure during PTCA.¹ Since then there have been many refinements in stent technology and there are now three types of stent in common use. The Palmaz–Schatz stent is composed of two articulated, slotted stainless steel tubes of variable length and is only 0.08 mm thick (figure 1). The Gianturco–Roubin stent is made of stainless steel wire (0.15 mm thick) arranged longitudinally in a sinusoidal coil. The Wiktor stent has a 0.13 mm tantalum wire arranged as a circumferentially oriented, sinusoidal coil. All three types of stents are balloon mounted and expanded by balloon inflation. The different stent designs result in different profiles, radial strength, flexibility and fluoroscopic opacity.

Standard PTCA procedures are used to deploy stents. An angioplasty guide catheter is positioned at the ostium of the coronary artery. The size of the artery and the severity of the stenosis is assessed by quantitative coronary angiography. Only arteries which are 3 mm or larger at the site of the stenosis are suitable for coronary stent deployment. A fine guidewire is placed in the lumen of the artery and skilfully advanced through the stenosis to the distal artery. Tight stenoses may have to be pre-dilated with a standard angioplasty balloon before stenting. The stent, mounted on an angioplasty balloon, is then carefully placed within the stenosis and deployed by rapidly inflating the balloon to high pressure. When the balloon is deflated the stent should remain expanded against the artery wall (figure 2). Further inflations within the stent may be necessary to ensure optimal deployment. The type of stent used depends upon the characteristics of the vessel (eg, tortuosity) and the stenosis (eg, length, side branch involvement), as well as operator experience.

Abrupt vessel closure is usually due to intimal wall dissection and this occurs in 4% to 11% of patients undergoing PTCA.^{2–6} The resulting acute myocardial ischaemia may lead to death (8%) or myocardial infarction (20%),⁶ and for many years emergency coronary by-pass surgery (CABG) has been the only solution. There is a high peri-operative mortality (6.4%) and morbidity (40% infarction) associated with emergency by-pass surgery compared with elective surgery.⁷

After PTCA the presence of a dissection flap on angiogram, particularly associated with progressive lumen narrowing, is a strong indicator of abrupt vessel closure.⁶ Deployment of a stent at the entry site of a dissection seals the dissection and prevents the closure of the vessel lumen. Many operators would stent the entire length of a dissection rather than just the entry site.⁸ In addition, abrupt closure without apparent dissection, possibly due to elastic recoil, can be treated with stents.

In these so-called bail-out situations, stents can be successfully deployed in the vast majority of patients (>96%) which reduces the requirement for emergency coronary by-pass surgery to less than 1%.⁹ In 301 patients with abrupt vessel closure treated with a Palmaz–Schatz stent, the mortality was 1.3% and the myocardial infarction rate was 4%.⁹ Comparable data have been published for Gianturco–Roubin stents.¹⁰ The time delay to deployment of the stent is crucial in bail-out situations. Those patients who already have total vessel occlusion at the time of stenting are at increased risk of myocardial infarction compared with those with subtotal or threatened occlusion.¹¹

The achilles heel of PTCA is re-stenosis; within 6 months of successful PTCA the narrowing has recurred in 30%–45% of *de novo* lesions in native coronary arteries, even with experienced operators.¹² Two randomised trials, involving a

Figure 2 This diagram shows how the unexpanded stent, mounted on a deflated angioplasty balloon, is placed within the diseased segment of coronary artery. The stent is deployed by inflating the balloon and then remains expanded against the artery wall

total of 930 patients with angina, have confirmed that electively deployed Palmaz–Schatz stents substantially reduce the re-stenosis rate compared with standard balloon angioplasty.^{13,14} In the European Benestent trial, the re-stenosis rate was 32% after conventional balloon angioplasty, compared to 22% after stent implantation.¹³ The reduction in re-stenosis rate was associated with a reduction in major clinical events in the group randomised to stents. A similar reduction in re-stenosis was observed in the STRESS trial (42% *vs* 32%)¹⁴ which was based in the US.

Lesions in vein grafts have a higher re-stenosis rate than native vessels and stents appear to reduce the re-stenosis rates in these vessels too, although randomised trials are currently still in progress. An angiographic re-stenosis rate of 30% at six months was reported following Palmaz–Schatz stents deployment to treat abrupt vessel closure after PTCA and this is superior to that expected in this subgroup.⁹

There are some technical difficulties with stent implantation. Visualisation of the thin metal stent before deployment requires high quality fluoroscopy imaging to allow its accurate placement within the stenosis. This is particularly true of the stainless steel stents. Displacement of the stent from the balloon on which it is mounted may occur and may result in loss of the stent into the systemic circulation. Fortunately, this uncommon occurrence rarely results in clinical sequelae.

The biggest problem with coronary stents has been thrombosis within the stent. Initial clinical experience suggested that there was a tendency to thrombosis in the first weeks after implantation. After this period, as the stent becomes endothelialised, the risk of thrombosis is minimal. Aggressive antiplatelet and anticoagulation regimes with aspirin, heparin and warfarin have reduced the risk of stent thrombosis to approximately 3% to 4% in patients after elective stenting.^{13,14} However, after stent deployment for abrupt vessel closure the stent thrombosis rate remains high despite anticoagulation (8% to 16%).^{11,15,16}

The use of stringent anticoagulation regimes has resulted in vascular access complications (pseudo-aneurysms and fistulae) and bleeding complications in up to 10% of patients.^{13,14} The need for meticulous anticoagulation control means that patients must stay in hospital for 4–5 days after stent implantation rather than the usual 1–2 days after balloon angioplasty. If the femoral artery has been used as the vascular access site, then the patients usually remain in bed during their hospitalisation. The cost of the extra days in hospital, and anticoagulation, as well as the stent itself, make this type of therapy considerably more expensive than straightforward balloon angioplasty. It can be argued that these extra costs are offset by the reduced re-stenosis rate and hence the reduced need for further intervention.

Developments in coronary stents are aimed at making them technically more user friendly, less likely to cause thrombosis and reducing the re-stenosis rate even further. In theory, stents which are fully expanded allow rapid laminar blood flow in the lumen and have a lower tendency to thrombosis. The use of new high-pressure non-compliant balloons to fully deploy stents and embed the struts against the vessel wall may reduce the need for anticoagulation.

Figure 3 Coronary angiography in this 57-year-old patient with unstable angina showed a critical mid-course stenosis in the dominant right coronary artery (A). After pre-dilatation of the stenosis with 2.5 mm angioplasty balloon, a Palmaz–Schatz stent was deployed using a 3.5 mm balloon. This stent is virtually invisible with angiography but there was no significant residual stenosis at the site of stent deployment (B). Intravascular ultrasound, scanning from within the lumen of the coronary artery itself, confirmed that the struts of the stent were fully deployed against the vessel wall (C). The patient was discharged home after 48 hours and has remained asymptomatic since the procedure

Learning points

- stents are used to treat the acute complications of PTCA such as vessel wall dissection
- stents significantly reduce the re-stenosis rate after PTCA
- intravascular ultrasound allows optimal deployment of intracoronary stents

Intracoronary ultrasound can be used to confirm that the stent is optimally deployed (figure 3) and it is probably superior to standard angiography.⁸ Colombo and colleagues used intracoronary ultrasound after stenting and then treated their patients with antiplatelet therapy (aspirin or ticlopidine) without anticoagulation. They report a very low rate of stent thrombosis (1.6%) over a six-month follow-up.⁸ This strategy reduces one of the major problems associated with coronary stents but at present intravascular ultrasound is not widely available and is expensive.

Another development to combat stent thrombosis, is the use of stents coated with a polymer membrane that delivers anticoagulant agents locally. Clinical trials of these stents are currently ongoing and the results are awaited with great interest. The polymer membrane coating on stents can be used to deliver other pharmacological agents (eg, antiplatelet and vasodilator drugs) which may reduce the rate of re-stenosis.¹⁷ It is anticipated that local delivery of comparatively high concentrations of these agents to the vessel endothelium at the site of stent implantation may reduce neo-intimal hyperplasia. Local emission of beta-particles from ³²P-impregnated titanium wire can also halt intimal smooth muscle hyperplasia and in animal studies these radioactive stents inhibit the re-stenosis process.¹⁸ In addition, future generations of stents may also be biodegradable.

Coronary artery stents have revitalised coronary angioplasty by reducing the re-stenosis rate and providing effective safe treatment for the acute complications of PTCA. With further improvements in deployment techniques and a reduction in the complexity of anticoagulation after stent deployment, the use of stents will continue to expand.

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