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What You Need To Know – Coronary Stenting – What's New in the Horizon?

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INTRODUCTION

Coronary stenting has in recent years emerged as a significant breakthrough in the field of interventional cardiology. There has been an explosive use of this device in coronary interventional cases, in as much as 70% to 80% in some of the high volume centres. The role of coronary stenting was firmly established following the results of the European-based Benestent[1] and the North American-based STRESS studies[2], which showed a significant reduction in the rate of restenosis compared to conventional balloon angioplasty. Long-term implantation also seems to provide continued vessel patency, no increase in major adverse events and reduced rates of repeat revascularisation. In addition, intracoronary stenting also improves the acute safety of a procedure by minimising the risks of abrupt closure. Further refinement of coronary stenting techniques and the use of effective antiplatelet regime[3-5] have made the procedure even safer by reducing the incidence of stent thrombosis.

Through innovative designs, many different stents are now available to interventionists to address even the most complex of lesions. Hence, a lesion-specific approach is now advocated whereby specific stent is chosen for a particular type of lesion or vessel based on its unique design.

Stent types and classification

As many as 30 different stent designs are in use in the world. Stents may be classified based on their predeployed repeating 'cell' pattern of metal construction (slotted tube, coil or mesh) and nature of the stent delivery systems (self-expandable or balloon-expandable). With the abundance of new stents, there is an urgent need for a "how-to" manual to help interventional cardiologists through the plethora of stent brands, types, structures, patterns, strengths, diameters and lengths.

Recently, a stent classification system was proposed by Jost[6] which was based on structural characteristics of the stents. This include original slotted tube stents (eg. Palmaz-Schatz), second generation tubular stents (eg. Crown, MultiLink, NIR), self-expanding stents (eg. Wallstent), coil stents (eg. Crossflex, Gianturco-Roubin) and modular zigzag stents (eg. AVE GFX). A summary of current stent designs is shown in Table I.

In general, slotted-tube systems, characterised by the PS stent, are characterised by high vessel surface area coverage, high radial strength and consistent circumferential deployment pattern. Coil stents provide for greater flexibility, conformability to the target vessel tortuosity, and access to side-branches but have significant intrinsic recoil. Mesh-design stents, found in many of the second generation tubular stents, are a hybrid of slotted tube and coil features. They possess the sizing strategies and deployment mechanics of slotted tube stents; and flexibility, conformability and side-branch access of the coil stents.

New stent designs

In recent years, many new stents have been added to the market. Whether the differences in designs and materials of these new stents will result in superior or similar clinical outcomes compared to established stents remains to be demonstrated in controlled "stents versus stents" trials. Most of the initial clinical experience of these new stents come from industry-sponsored registries rather than randomised comparative studies.

Palmaz-Schatz Crown stent (Cordis/Johnson and Johnson)

The PS Crown stent is a modification of the original PS stent, the reference stent against which most new stents are compared. It features a continuous slotted-tube design in a repeating sine wave pattern without articulation sites. It has a lower profile and slightly better flexibility compared to the older PS stent design. In an expanded state, the stent has a metallic surface area of 20% with little shortening on full expansion. It has been approved by the US Food and Drug Administration for clinical use following completion of a safety and efficacy registry study. PS Crown stent is best for lesions in proximal, mildly calcified, large and straight vessels where a high radial force of stents is required. A third generation stent, the PS MiniCrown stent, is currently being evaluated. It is designed with a reduced number of rows of slots and strut thickness with prime indication for use in small vessels, even down to 2.25 mm vessels.

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Table I – Coronary artery stents

Type	Manufacturer	Product name	Material
Self expanding stents	Schneider	Wallstent	Cobalt alloy
	Scimed	Radius	Nitinol
Balloon expandable	Cook	Gianturco-Roubin	Stainless steel
coil stents	Cordis	Crossflex	Stainless steel
	Medtronic	Wiktor	Tantalum
Balloon expandable	Cordis	Palmaz-Schatz	Stainless steel
tubular stents	Cordis	Crown	Stainless steel
	Scimed	NIR	Stainless steel
	Medtronic	Bestent	Stainless steel
	Terumo	Terumo	Stainless steel
	Guidant	MultiLink	Stainless steel
Balloon expandable	Cordis	Crossflex LC	Stainless steel
hybrid stents	AVE	GFX	Stainless steel
	InvaTec	InFlow Goldflex	Stainless steel

NIR stent (Medinol, Boston Scientific, Tel Aviv, Israel)
The NIR stent is made of stainless steel welded into a tubular structure of five, seven and nine continuous cells. Its structure combines radial support with flexibility, especially for the short seven-cell NIR stent. The stent negotiates bends quite well because of its good profile and radial force. Its trackability is however felt to be less compared to the GFX or Crossflex stents. The FINESS study[7] demonstrated a high 6-monthly procedural success rate (98%) and event-free (82%) survival. The rate of restenosis with the 16 mm NIR stent was similar to the 15 mm PS stent (16.5% vs 13.3%, NIR vs PS, P = NS) but restenosis increased dramatically with the long 32 mm NIR stent[8].

MultiLink Duet (Guidant, Santa Clara, CA)
This is an improved version of the proven MultiLink stent, which has a track record of low rate of angiographic restenosis at 6 months[9,10]. Its design is based on the tested corrugated ring pattern of the MultiLink stent which provides for good flexibility, trackability, conformability and crossability. The Duet stent comes with enhanced radiopacity and radial strength due to its increased strut thickness. It is mounted on a high pressure, minimally compliant delivery balloon systems which potentially obviate the need for an additional post-dilatation balloon.

InFlow GoldFlex stent (Invatec InFlow Dynamics, Munich)
This is a gold-plated hybrid stent which is designed to provide good visibility as well as improved flexibility compared to the previous InFlow Gold stent. It is manufactured in the form of interconnected sinusoidal waves with good metallic vessel surface area ratio. Long-term results regarding the effect of gold stents on vessels, specifically restenosis, remains unavailable.

Bestent (Medtronic, Minneapolis, MN)
Bestent has a unique serpentine mesh structure that is free of welding point. Its advantageous dual radiopaque distal gold markers allows for precise positioning of the stent. The stent is also suited for small vessel implantation because of its relatively low amount of metal in an expanded state.

Terumo stent (Terumo, Japan)
Terumo stent is a tubular stent designed with a monolink structure that offers good flexibility and trackability. Mounted on a non-compliant balloon, it has a balloon tip that is low in profile that offers high crossability. Most of the initial experience come from Japan. A local trial has been recently completed to evaluate this new stent.

Crossflex LC (Cordis/Johnson and Johnson)
This is the latest hybrid slotted-tube stents which combines the coil design of the Crossflex and the scaffolding property of a second-generation tubular stent. It provides excellent trackability and flexibility and is suited for both proximal and distal lesions. Its high radial strength also enables it to be used for ostial lesions, chronic occlusions and bifurcation lesions. A multicentre registry has been set up to evaluate this stent.

GFX stent (Arterial Vascular Engineering, Santa Clara, CA)
This is among the most popularly used stent in Europe, because of its remarkable trackability and flexibility. It is excellent for negotiating acute bends and allows good access to side branches, and is ideally suited for bifurcation stenting. Its radial strength is less than that of PS stent and long-term clinical experience with it is lacking.

Magic Wallstent (Schneider, Bulach, Switzerland)
Wallstent is the prototypical self-expanding stent with a wire mesh design that is controlled by a retractable sheath. This stent provides greater visibility, less shortening upon stent expansion and better flexibility compared to the older Wallstents. The profile of the stent is considered to be less than ideal and has a high metal content which limits its use in small vessels or bifurcation lesions. Precise positioning of the stent is still a challenge owing to the inherent shortening characteristic of the stent during deployment.

Custom-designed stents
With percutaneous treatment now being considered even for complex lesions previously deemed to be unamenable to coronary angioplasty, the industries have responded by designing customised coronary stents for specific lesions.

Bifurcation stents
Several designs are currently being evaluated for bifurcation lesions. These include the Jostent B stent which has differing configurations and sizes of the cells at either ends. At one end, the cells are connected by V-shaped bridges which is similar to the previous

Jostent M while the other end has larger cells connected with straight bridges. The latter allows for easy access to bifurcating side branches. Another stent in the pipeline is the Bard Bifurcation stent which is shaped like a Y and is mounted on 2 balloons. The main body of the stent is a single coil, through which two balloons pass. The balloons diverge at the crux of the Y to pass separately through the two arms. This stent is currently being evaluated in animal studies.

Covered stents

The design of the covered stent is another novel approach to stent customisation. The prototype is the Jostent Coronary Stent Graft which is constructed with a sandwich technique whereby an ultrathin layer of expandable PTFE is placed between two stents with reduced strut thickness. The graft is coated with heparin to reduce the risk of thrombus formation. The covered stent is of potential value in four situations, namely, treatment of coronary aneurysms, acute or imminent coronary perforations, saphenous vein graft stenoses and recurrent in-stent restenosis[11].

The use of a segment of autologous vascular tissue for stent cover has also been reported both for elective indications[12] and in the setting of acute myocardial infarction[13]. Commonly, a segment of the cephalic or ulnar artery is harvested and crimped onto the stent for deployment.

Radioactive stents

The use of stents as a platform for the delivery of radiation to the vessel wall has generated intense interest, driven by the potential of this strategy in combating in-stent restenosis. Effective doses of radioactivity can be delivered to all levels of the vessel wall from stent-bound radioactive sources. Most of the current interest has been focused on β-emitting stents because of the initial success in reducing neointimal proliferation in animal studies[14-15].

Stent coatings

The use of materials to coat metal stents in a bid to reduce inherent stent thrombogenicity and reduce incidence of in-stent restenosis has long been the interest of the industries. The materials used may either be synthetic (eg. polyurethane, poly-L lactic acid) or naturally occurring substances (eg. heparin, phosporyloline). Commercially available coated stents include the gold-coated InFlow and NIRoyal stents; the heparin-coated Cordis/Johnson & Johnson Palmaz-Schatz, Wiktor and Jostent. Early experience with the use of heparin-coated stents in the BENESTENT II trial showed a very low rate of subacute stent thrombosis (< 0.2)[16].

Endovascular stents as a reservoir and vehicle for local delivery of drugs are also being looked at. Several drug-polymer systems have been devised which allow for sustained release of the drugs to the local vessel wall over a desired time period. These include the InFlow hirudin and Iloprost-eluting stents[16] and the glycoprotein IIb/IIIa eluting cellulose-polymer-coated stent[17].

The interest in the use of biodegradable stent has diminished in recent times. To be effective, the drug-releasing biodegradable stent must be biocompatible, must not evoke inflammatory reaction and must provide sufficient initial support to oppose the retracting force exerted by the diseased vessel. One such model is the Duke Biodegradable stent which is made of specialised form of poly-L-lactide. Early experience with this stent has been promising[18].

CONCLUSIONS

As the global experience and interest in coronary stenting continues to increase, their use is likely to expand and cover a broader range of complex lesions. Future stents will focus more on improved designs, coatings, and being effective drug and radioactive material delivery stations. The final goal will be to achieve even greater long-term clinical benefits for patients with coronary stenoses.

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