

Devices and Techniques for Endovascular Surgery:

Catheters, Stents, Coated Stents, and Stented Grafts

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Abstract

Endovascular/minimally invasive surgery has undergone rapid innovation and growth. From crude, stiff, large-bore tubes that were used initially to evaluate vascular structures, some of the new catheters and wires are only a little bigger than the human hair, which permits their passage in vessels previously thought inaccessible. Closed arteries and veins now can be effectively traversed and blood flow restored by the use of balloons and metallic stents to maintain the integrity of the vascular lumen.

Key Words: Catheters, coated stents, endovascular devices, stents, stented grafts, endovascular surgery.

Catheters

ANGIOGRAPHIC CATHETERS can be divided into two broad categories, flush and selective. Whereas a flush catheter may be adequate to serve a therapeutic goal, a selective catheter is used for diagnosis. Both types of catheters come in a variety of shapes and sizes. Flush catheters are typically larger in caliber than selective catheters, which vary in diameter from 4 F to 6 F or greater (3 French = 1 mm) (Fig. 1).

The standard inner diameters of a diagnostic or flush catheter are 0.035 inch and 0.038 inch. Standard guide wires can be used. Construction and materials are important to consider when choosing the catheter. Materials used are teflon, nylon, polyurethane and polyethylene. Some have additional hydrophilic coating that makes the catheter slippery and easier to manipulate into an otherwise inaccessible vessel. To improve rotational torque, some catheters have a braided stainless steel mesh incorporated into their walls.

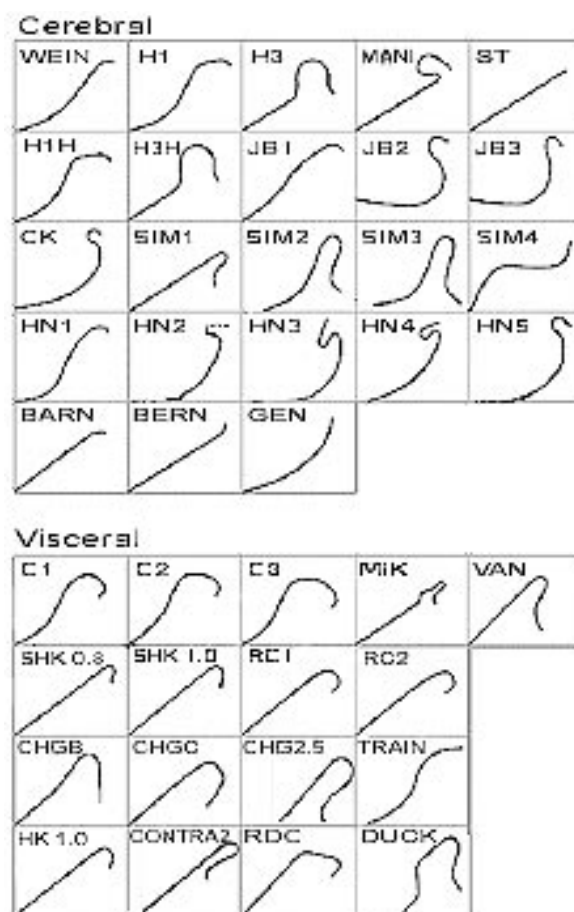


Fig. 1. A multitude of catheter shapes and sizes is available. Diagram courtesy of Boston Scientific, Natick, MA.

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To minimize the risk of stretching or fracture, catheters must have high tensile strength — yet still have a low coefficient of friction. Catheters must be able to resist high burst pressures associated with high injection rates, and still maintain their predetermined shape in order to pass through tortuous vessels. They must also have low thrombogenicity.

Catheters and their tips must be sufficiently radiopaque to aid fluoroscopic guidance. Since a large amount of contrast must be injected through the catheter into the vascular system in a relatively short period of time, a multi-hole catheter is used to avoid a dissection or rupture, which may occur following the use of an end-hole catheter.

Flush Catheters

Flush catheters come in various sizes and shapes. Some are straight, or shaped like a pigtail, a shepherd's crook, or a tennis-racket (Fig. 2). These can be easily manipulated into tortuous vessels, such as a contralateral iliac artery, and still provide excellent flow rate. But the end outcome is similar — high flow rate and no injury to the vessel, because contrast is delivered to a wide area. These catheters typically come in either 4 or 5 F sizes, but are available in a wider range of 3 to 8 F. To obtain accurate measurements within a vessel, some flush catheters come scored with centimeter markings that are radiopaque. A good example is a pigtail catheter that is routinely used to measure aneurysm length, and the distances from the adjacent vessels (Fig. 3)

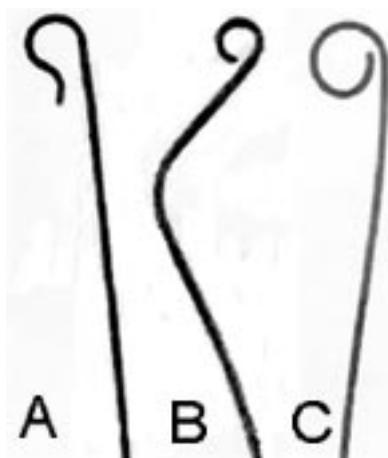


Fig. 2. Common flush catheters used in today's angiography. (A) Omniflush. (B) Grollman. (C) pigtail.



Fig. 3. AP view of the abdomen in a patient with an infrarenal abdominal aortic aneurysm. A marker pigtail catheter is positioned above the renal arteries. Following intravenous contrast injection, the abdominal aorta and the iliac system arteries are visualized.

Typically larger flow rates and stiffer catheters are helpful in pulmonary angiography, where a 6.5 F Grollman or Montefiore catheter can be used effectively, since the shapes make the manipulation through the heart chambers and into the pulmonary arteries and their branches much simpler.

Selective Catheters

Selective catheters come in many more shapes and sizes with preformed tips that can facilitate the selective catheterization of virtually any vessel. Choosing the correct one requires a consideration of the anatomy, vessel location and size, and possibly the disease involved.

Some catheters, such as the Berenstein catheter, are used more frequently than others (Fig. 4). This catheter is shaped like a small hockey stick and can be torqued in any direction. Similar catheters are available with varying curvatures, and lengths of tip.

When an artery or vein originates at an acute angle from its parent vessel, such as a left subclavian or left carotid artery, reverse curve catheters can be extremely helpful in engaging the lumen. Many such catheters exist. Simmons 1 and 2 have long been favorites (Fig. 5). Other catheters, such as the Mikaelsson and Sos-

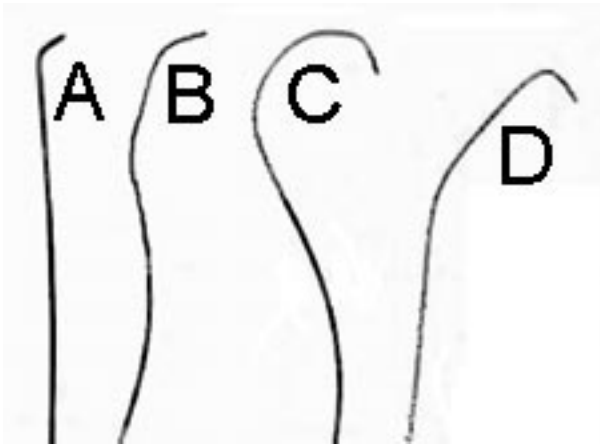


Fig. 4. Typical selective angiographic catheters: (A) Berenstein. (B) Headhunter. (C) Cobra. (D) spinal.

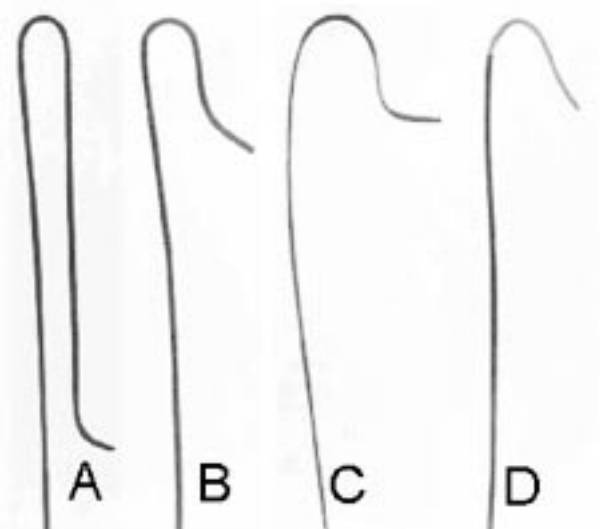


Fig. 5. Reverse curve catheters: (A) Bookstein. (B) Simmons. (C) Shetty. (D) Viscera hook.

selective, can provide quicker access to visceral or renal vessels. These reverse curve catheters, in which the tip is advanced into the vessel by withdrawing the catheter at the puncture site, must first be reformed into their original shape in the thoracic aorta prior to use.

Microcatheters

When a vessel is smaller than a conventional catheter, interventionalists resort to using microcatheters. These are typically 3 F or smaller and are placed coaxially through either a 4 or 5 F selective catheter. A number of factors influence the choice of a microcatheter. When a higher flow rate is required, a catheter with the largest possible inner lumen is preferred. Long

and tortuous vessels require a more maneuverable catheter with hydrophilic coating that is trackable. The indications for preferring a particular catheter vary depending on whether its intended use is diagnostic or therapeutic, such as delivering chemotherapeutic agents into hepatic lesions, or embolizing them with various agents. The use of small catheters is helpful for embolizing bleeding vessels, vascular malformations, and small aneurysms.

Infusion Catheters

The infusion catheter is a variant of a flush catheter. The infusion catheter contains multiple side holes that are much smaller than one would find on a pigtail or similar catheter. A few varieties exist, but suffice it to say that the principle of delivering a thrombolytic agent into a clot is a constant feature of them all (Fig. 6).

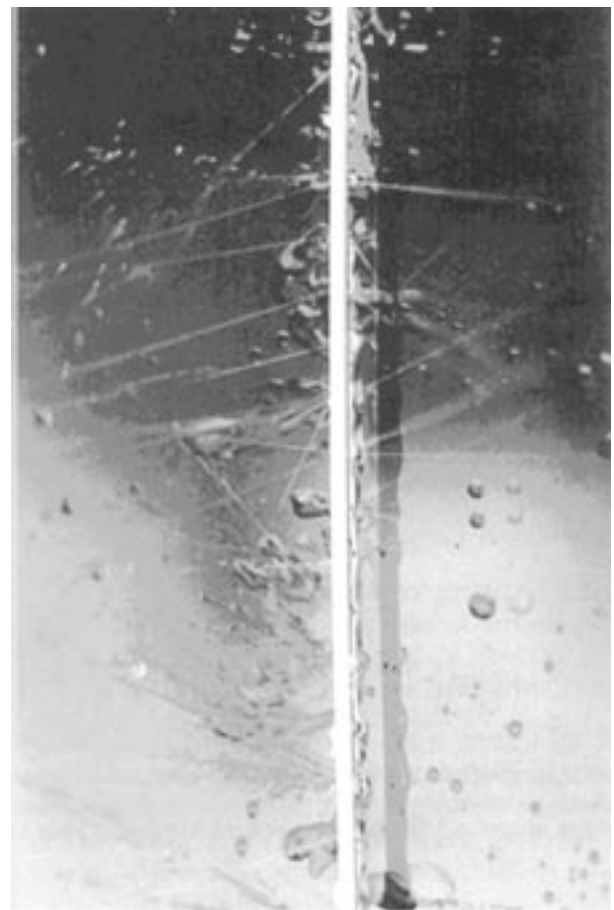


Fig. 6. An infusion catheter is designed to deliver medication over a predetermined distance with wide coverage. The side holes are numerous and much smaller than on a flush catheter.

Sheaths

The third type of catheter is one with a vascular sheath. They are used primarily to prevent oozing or hematoma formation at the access site, and when multiple catheter exchanges and a prolonged procedure time are expected. Most of these have a side-arm through which contrast can be injected, or fluids administered. These are also used to provide extra support and stabilize smaller, less sturdy catheters in place. An example would be a 60 cm long, 6 F sheath, positioned with the tip at the renal artery opening, with a smaller balloon catheter delivering a stent for the artery. Continuous contrast administration through the sheath aids in exact positioning of the balloon-stent combination (Fig. 7).

Angioplasty and Stents

The first true stent was developed by Palmaz in 1985; it remains the only FDA-approved device for peripheral arterial placement. Indications for the use of stents include suboptimal results after angioplasty (including recurrent or significant residual stenosis greater than 30% of lumen diameter, and a peak systolic arterial pressure gradient across the lesion of more than 10 mm Hg), complications of angioplasty or catheterization procedures (flow-limiting dissection or acute thrombosis), primary treatment

of iliac artery occlusive disease, and primary treatment of ulcerative lesions in peripheral arteries with evidence of distal embolization and eccentric stenosis.

There are few contraindications to using a stent, such as a stenosis resistant to balloon angioplasty and arterial rupture after angioplasty. The second complication may be treated with a covered stent (a stent that has a material encircling the metal frame, thereby providing a contiguous coverage (Fig. 8). Relative contraindications include aneurysm within the vicinity of the stenotic segment and impaired pain sensation.

The intra- and post-procedural care of a patient undergoing stenting would include intravenous administration of 3000–5000 units of heparin immediately prior to stent deployment. A short course of anticoagulation (24 hours), with antiplatelet agents such as aspirin, or ticlopidine helps prevent immediate thrombosis of the device.

Immediately after stent placement, a thin layer of fibrin coats the luminal surface. Over several weeks, this layer of clot is gradually replaced by fibromuscular tissue. Reendothelialization of the stented vessel is thought to protect it from late thrombosis.

How the stents maintain vascular patency is a mechanism that is not completely understood. It is thought that wall stress imposed by the stent retards the process of intimal hyperplasia.



Fig. 7. A sheath tip is resting within the origin of the left renal artery; this facilitates precise placement of an over-the-wire stent. Additionally, contrast is being administered through the sheath, allowing for constant visualization of progress.

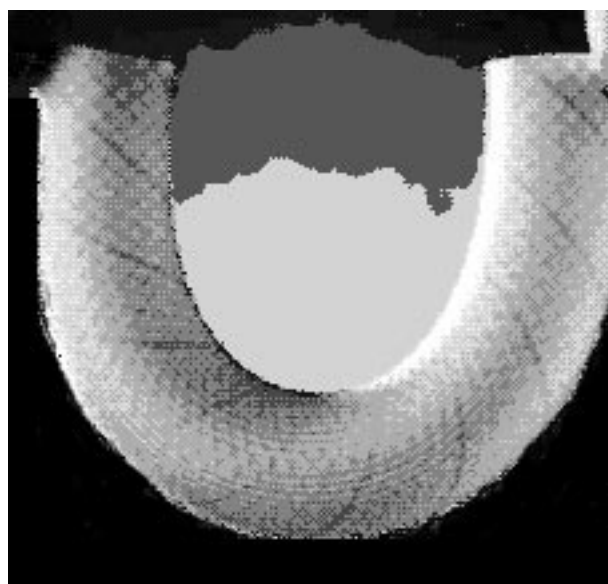


Fig. 8. Wallgraft. Self-expanding Wallstent with a fabric incorporated into the design, providing a solid tubular structure. Although this has FDA approval for use in tracheobronchial obstruction and fistulae, off-the-shelf uses include vascular and biliary work.

At the same time, dynamic thinning of the media is a constant feature of the stented arteries.

The most important properties of these devices are hoop strength, longitudinal flexibility, elastic and plastic deformation, length and composition. There are basically two stent designs: balloon-expandable and self-expandable.

Balloon-Expandable Stents

Balloon-expandable stents are premounted tightly onto a balloon-catheter, and are delivered into a lesion in a constrained form. They are deployed when the balloon is inflated. The benefit of using this type of stent is that it can be positioned precisely in a lesion. Although the approximate diameter is predetermined, the exact diameter of the expanded stent depends on what diameter balloon is used for the inflation. These stents retain the diameter imposed by the angioplasty balloon, but also are compressed externally.

The Palmaz stent (Cordis/Johnson and Johnson, Warren, NJ) is a prototype of a balloon-expandable stent. It is rigid and made of stainless steel. Many sizes are available, varying in length from 8–75 mm, and in diameter from 3–12 mm. The stent shortens minimally as the balloon expands. This allows for a precise positioning. Because this type of stent has only minimal longitudinal flexibility and is subject to permanent plastic deformation, it should be placed into a relatively straight vascular segment, such as a renal artery or superior mesenteric artery, and not at sites such as dialysis grafts, femoral or other joints, or thoracic outlet veins, where an extrinsic force could crush it.

One example of a newer balloon-expandable stent is a Genesis transhepatic biliary stent. It represents the next generation of the Palmaz type, having much better trackability and higher radial strength. It comes premounted on a smaller profile balloon catheter, and is 6 F guide catheter compatible (Figs. 9–12).



Fig. 9. (A) Genesis stent. (B) After removal of the stent, the balloon appears to have been nearly flush with the stent.

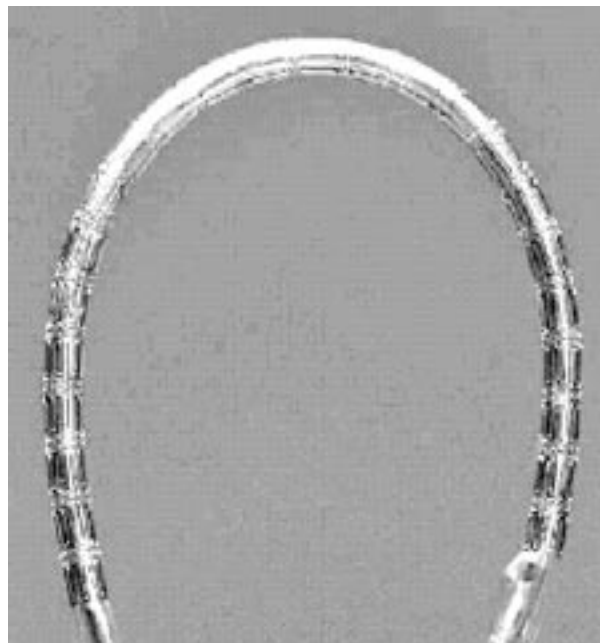


Fig. 10. A long Genesis stent demonstrates marked flexibility, compared to older generation of similar technology.

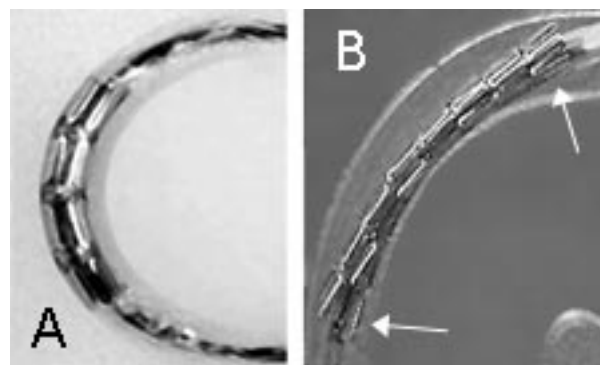


Fig. 11. Newer technology allows for a more flexible stent design. (A) Stent retains its crimped shape, whereas in B, stent demonstrates flaring of the tips (arrows).

Self-Expanding Stents

Self-expanding stents are held in place within a catheter, and are deployed by removing the constraining sheath, exposing the stent to the vessel. The final diameter is predetermined, but is also a function of the elastic recoil of the vessel wall.

A Wallstent (Boston Scientific, Natick, MA) is a prototype of a self-expanding stent. It is composed of stainless steel filaments woven in a cross-hatched pattern. It also comes in many sizes, with the diameter ranging from 5–24 mm, and a fully deployed length of

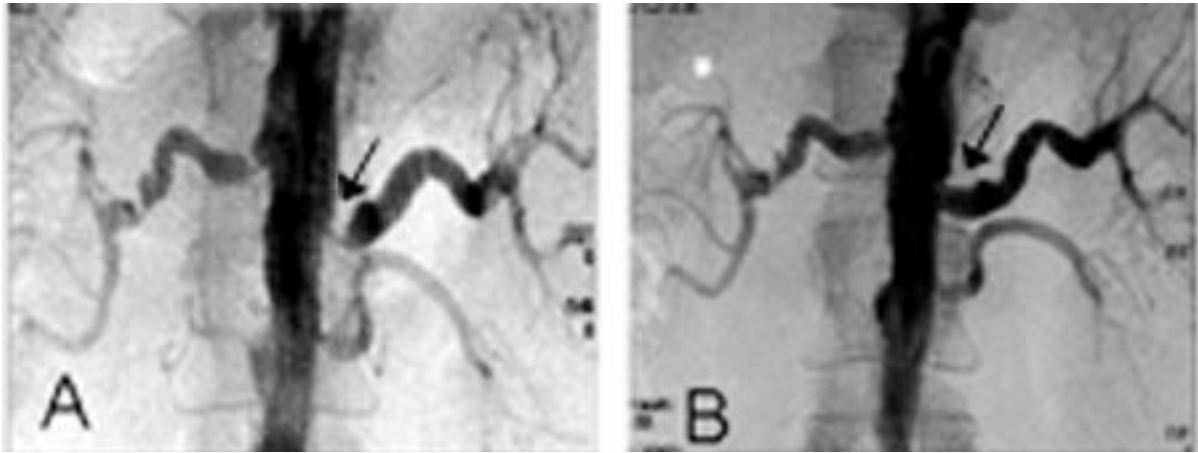


Fig. 12. Before (A) and after (B) bilateral renal artery stenting with Genesis 6 mm × 15 mm stents to restore luminal patency (arrows).

20–94 mm. Because the compressed length of the stent is significantly longer than its expanded length, placement is much less precise than with the balloon-expandable stents. These stents have almost no plastic deformity but considerable elastic deformity and longitudinal flexibility. Because of these characteristics, maneuverability and delivery of the stent catheter through tortuous vessels and tight curves is particularly easy (Fig. 13). Newer technologies and materials make it possible to manufacture stents that have higher tensile strength, increased visibility, smaller profile of the delivery device, and decreased thrombogenicity.

The new self-expandable catheters include SMART (Shape Memory Alloy Recoverable Technology (Fig. 14) and Precise, an 0.018” system (Cordis, Johnson and Johnson company, New Brunswick, NJ). These stents are made from nitinol, a polymer of nickel and titanium, giving them much more flexibility at room tem-

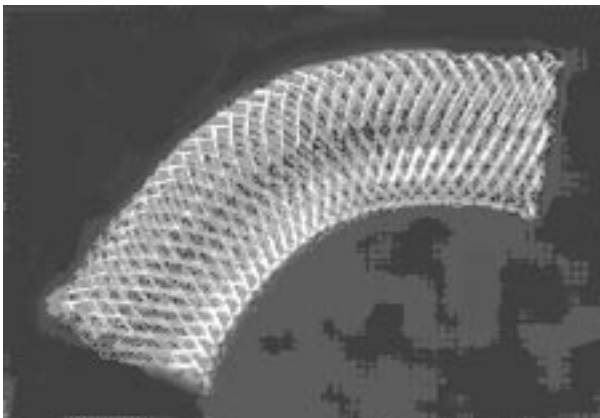


Fig. 13. Wallstent. Diagram courtesy of Boston Scientific, Natick, MA.

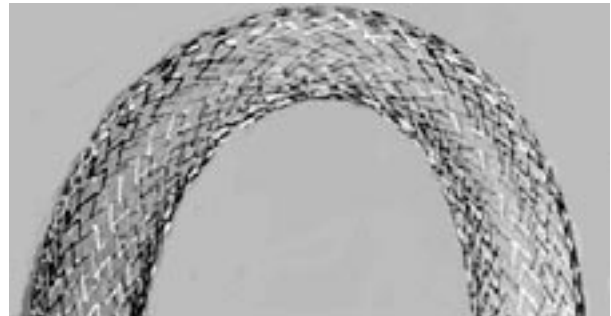


Fig. 14. SMART stent.

perature, and a rigid, predetermined shape at body temperature. An excellent improvement over their competitors is their minimal shortening, allowing for much more accurate positioning.

The use of newer materials and manufacturing technologies allows for a better surveillance of the stented vascular structures. In the past, artifacts from the implantable metal devices such as stents produced marked artifact on imaging studies, such as CT and MRI. However, today, non-invasive follow-up of patients can be performed with little or no difficulty in assessing the luminal patency and/or stenosis (Fig. 15).

Stents, unfortunately, are not without long-term problems. Their widespread use has led to an appreciation of the occurrence of in-stent restenosis (ISR). This occurs primarily as a result of proliferating smooth muscle cells and extracellular matrix. ISR is more apt to occur in women, in patients with diabetes, and in cases of long lesions with significant total plaque burden after stenting (assessed by intravascular ultrasound), small vessel diameter, and with the use of multiple stents and certain types of stent.



Fig. 15. MRA image of bilateral renal arteries following placement of platinum stents (arrows).

Mechanical strategies and systemic drugs have been employed to inhibit the neointimal hyperplasia. However, the most promising modality has been the recent use of drug-eluting stents (1).

A distinction must be made between drug-eluting stents and simple coated ones. Simple coated stents are covered either with a polymer (phosphorylcholine silicon carbide) or with a drug directly applied to the metal (e.g., heparin-coated stents and paclitaxel-coated stents). These are primarily used to decrease the thrombogenicity of the metal. On the other hand, drug-eluting stents have both a polymer and a drug spread over the metal, allowing for slow release of the drug directly into the adjacent tissue, targeting the process of neointimal hyperplasia. Numerous combinations of coatings have been studied. Some have proven to actually increase the rate of restenosis or to be proinflammatory (2).

Recent studies using drug-eluting stents containing rapamycin, an immunosuppressive agent, and paclitaxel have demonstrated potent cell cycle inhibitory effects. Both drugs inhibit cellular proliferation by different mechanisms (1).

Experience with the rapamycin eluting stent was recently reported in a 45-patient registry (1). At one year, there was no angiographic or intravascular ultrasound (IVUS) restenosis, nor were there stent-related adverse events. The results of the first randomized double-blind study (RAVEL) using the slow release combination of

rapamycin, were reported at the European Society of Cardiology in September 2001. In this trial, for the first time in the history of vascular intervention, the incidence of in-stent-restenosis (ISR) in the treatment arm was 0% compared to 26% in the control group (2).

Paclitaxel (Taxol, Bristol-Myers Squibb, Princeton, NJ) is a microtubule-stabilizing compound with potent antitumor activity. Results similar to that of rapamycin have been found. ASPECT (Asian Paclitaxel Eluting Stent Clinical Trial) demonstrated a restenosis rate of 4% vs. 27% in a control group. ELUTES, a European dose-ranging study presented at the American Heart Association 74th Scientific Sessions, showed comparable results of ISR of 3% vs. 21% in bare metal group. TAXUS I trial used a polymer-based paclitaxel eluting NIR stent (Boston Scientific, Natick, MA), with a 6-month restenosis rate of 0% compared to 11% in the control group (2). More studies enrolling larger groups of patients are needed to substantiate these encouraging results.

Although rapamycin and paclitaxel have been most studied, other combinations are also being investigated. These include tacrolimus, dexamethasone, batimastat, rapamycin analogs, phosphorylcholine, liposomal encapsulated PGE-1, and c-myc antisense oligonucleotides (2). Additionally, prospective experimental therapies include creating molecules of DNA and RNA to inhibit specific genes involved in the ISR. Gene transfer techniques would be employed to introduce these agents to the desired location, to inhibit neointimal proliferation.

Conclusion

Long-term outcomes of these new techniques are yet to be reported. However, new advances in the technology as well as the technique are very promising. Additionally, patients who were considered inoperable just a few years ago now have the opportunity to reduce their existing disability and risk, and enhance the quality of their life.

References

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