PVD II: AORTOILIAC INTERVENTIONS

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I. Diagnostic Evaluation

Cross Sectional Evaluation

Access

For diagnostic arteriography prior to aortoiliac interventions, the choices for access include the ipsilateral and contralateral femoral approach, as well as the axillary or brachial approaches for patients without adequate femoral pulses. In general, the location of the stenosis or occlusion within the common or external iliac artery will determine whether contralateral or ipsilateral access is most desirable. For example, ipsilateral access is preferable to treat a distal external iliac artery stenosis. Wile the delivery systems of today's self-expanding stents allows for the negotiation of the iliac bifurcation (facilitating a contralateral approach), rigid, balloon expandable stents, are often best placed from an ipsilateral approach. The ipsilateral approach may be less desirable is some patients (females, small patients) due to the possibility of the introducer sheath limiting flow at the level of the common femoral artery. In these cases, the contralateral approach allows for better outflow after the intervention than the contralateral route due to the mechanical disadvantage of this approach.

Imaging Evaluation

Oblique images of the pelvis may be useful to help determine stent placement. In particular, the contralateral anterior oblique projection is helpful for determining the exact point of origin of the internal iliac artery and is therefore of use in deploying stents in the distal common iliac and proximal external iliac arteries. Additionally, a ruler may be a useful aid to bony landmarks. A marker/measuring catheter or guidewire may also be used to determine the size of the normal segment in order to assist in stent and balloon selection. Relying on bony landmarks and rulers on the field alone to position a stent is less reliable than a contrast injection with fluoroscopy to obtain a "mental road map" prior to stent deployment> If imaging equipment permits obtaining a reliable and visible digital road map, this technique may also be used and is often quite helpful during stent deployment.

Hemodynamic Evaluation

The role of hemodynamics in determining indications for an intervention as well as endpoints for aortoiliac interventions cannot be overemphasized. Remember that single-plane angiography provides a two dimensional portrayal of a three-dimensional structure (1). As a result, the actual degree of narrowing will vary depending on the image plane utilized. Hemodynamic measurements are more accurate than angiographic images in determining underlying stenoses and also have been demonstrated to predict clinical results of invasive interventions (2-4). The actual criteria utilized to determine the necessity of intervention of varies between centers. However, in 1979 Brewster et al attributed significance to lesions associated with a femoral artery systolic pressure gradient of >5 mm Hg at rest and >15 mm Hg after reactive hyperemia (1,5). Despite their revision in 1991 to an aortofemoral artery systolic pressure of at least 5 mm Hg or a decrease in the femoral artery pressure of at least 15% after flow augmentation (6), the initial criteria are still commonly utilized in many angiography and endovascular laboratories.

The most accurate method of measuring pressures in the setting of aortoiliac occlusive disease uses a two-transducer catheter system with one catheter in the aorta and a second catheter in the femoral or external iliac artery (1). A second method is the unilateral pullback technique while a third method involves simultaneous unilateral aortic and femoral artery pressure measurements with a femoral artery sheath and a smaller coaxial catheter (1). With the last method, an insufficient gap between the catheter and sheath may cause too much damping of the femoral artery pressure, resulting in a false pressure gradient. In general, pressures should be recorded with end-hole catheters so that the actual site of the pressure measurement cannot be disputed.

Treatment Planning

>90% of patients with inflow disease have obstruction of the common or external iliac arteries. Occasionally, obstruction may be limited to the abdominal aorta. The focal terminal aortic plaque is most commonly seen in younger females. Very rarely, total obstruction of the aorta and iliac arteries, or diffuse atherosclerotic narrowing of these vessels, is seen angiographically. If such patients do not have comorbid conditions that preclude bypass surgery, surgical treatment is preferred. However, technically successful results can be achieved in these patients percutaneously if the patients are considered to be at high risk for morbidity due to surgery, particularly if total aortoiliac occlusion demonstrates response thrombolysis.

II. Technique: Lesion Traversal

Experienced angiographers are usually able to readily achieve guidewire access across a stenosis. Use of a long-tapered spring-coil wire and a shaped catheter, or a steerable guidewire and catheter, or perhaps a variable diameter (0.018” to 0.035”) guidewire usually permits traversal of stenoses without dissection. Angled hydrophobic guidewires are popular, but are more prone to subintimal dissection and should be reserved for stenoses refractory to other methods.

Crossing an arterial occlusion, however, is often the most challenging part of a percutaneous aortoiliac revascularization procedure. Chronic arterial occlusions can be crossed using a number of techniques. In general, a straight 5F catheter is advances to within several centimeters of the occlusion and the lesion is gently probed with a straight spring-coil wire. If this wire does not cross the occlusion easily, then an angled hydrophilic wire is used. Using a constant spinning motion, the hydrophilic wire is gently advanced so that its tip remains freely mobile. The use of hydrophilic wires has greatly facilitated crossing chronic occlusions, and technical success rates from 81-95% have been reported (7,8). Care must be taken, however, to avoid passing the hydrophilic wire into a subintimal tract (9). If a subintimal tract is created, reestablishing passage into the true lumen from the same approach can be difficult or impossible. A subintimal passage is suggested by a spiral course of the wire during traversal, or if hand injections of contrast demonstrate smooth crescentic collections of contrast in the subintima. In some instances, the true lumen in a chronic occlusion may be totally obliterated, making subintimal passage necessary. If the true lumen of the vessel is entered immediately above and below the occlusion, successful revascularization can be achieved with stents (10).

There are techniques that can facilitate reentry into the true lumen when subintimal passage is observed. The first of these methods is to attempt traversal from the opposite approach, either around the bifurcation, which is preferred, or from an axillary or brachial approach. If luminal reentry is successful, the hydrophilic wire can be snared from the ipsilateral access site achieving through-and-through access (11). When treating common iliac artery lesions, similar results can be achieved from a contralateral approach utilizing a shepard’s crook type catheter, which is firmly pulled down into the occluded common iliac artery. In the vast majority of cases, one of the above techniques is successful in crossing the occlusion. If these methods fail, more aggressive techniques, such as using a catheter-sheathed curved needle to puncture into the true lumen from the subintimal tract, can be tried judiciously (12). On some occasions, distending the terminal aorta by inflating a compliant balloon, such as an occlusion balloon, can aid the passage of a guidewire antegrade or retrograde through the ostium of an occluded common iliac artery, which is usually the area most refractory to recanilization.

III. The Role of Thrombolysis in Chronic Iliac Artery Occlusion

Thrombolytic therapy for chronic iliac artery occlusions adds cost, requires hospital admission and prolonged immobilization, and carries the risk of bleeding complications. Primary recanilization can be done relatively easy at a single setting using stents with acceptable complication rates. Thus, it is clear that thrombolysis is not for every patient with chronic iliac artery occlusion.

If guidewire traversal is relatively straightforward, this suggests that soft thrombus is present. Contrast injection during occlusion traversal in this situation will often reveal filling defects; these patients may benefit from thrombolysis. If guidewire traversal is challenging, it is likely that a chronic occlusion is present with no acute thrombus. Contrast injection will usually reveal an atrophied lumen and no filling defects. Thrombolysis in such an artery offers no potential benefit.

Placement of the thrombolysis system into the iliac occlusion is preferably done from the contralateral approach; if this is not feasible to mechanical disadvantage, the ipsilateral approach is acceptable. Using a single multi-sidehole catheter, it is desirable to infuse the entire length of the occlusion, with the most proximal sidehole placed at the lead edge of the thrombus. Using a coaxial infusion system, the catheter is placed at the leading edge of the clot and the guide is embedded 2/3's into the occlusion and the infusion is initiated. In the days of urokinase (60,000-80,000 IU/hr), a success rate of 79% has been reported with complete lysis achieved in 55% (13). Successful lysis is achieved most often when performed for patients with less than 6 months of stable symptoms; when patients with over 1 year of stable symptoms undergo thrombolysis, successful lysis is observed in only 14% (14). Success with thrombolysis performed with both Reteplase (15,16) and Alteplase (17) prior to angioplasty and/or stent placement has been observed as well with more information regarding the technical aspects of these agents available in the thrombolysis workshop.

IV. Results

Percutaneous Angioplasty

Prior to the availability of stents, balloon angioplasty demonstrated excellent results in relieving atherosclerotic obstructions of the aorta and iliac arteries. Technical success rates in the most series are >90% and five-year patency rates from 54% to >93%, with a mean of 72% in Becker's review of almost 2,000 cases of iliac angioplasty (18). However, none of these series included "all comers" of patients with aortoiliac insufficiency, and thus "intention to treat" success rates or patency rates are not known. Focal lesions, particularly those located in this common iliac artery, responded most favorably to balloon angioplasty (19). Long stenoses, tandem lesions, or chronic occlusions respond less favorably to balloon angioplasty (19). Although some authors have described successful results of balloon angioplasty in iliac artery occlusions (20), most experience suggests a low technical success rate and high rate in this setting (21-23).

The treatment of significant infrarenal aortic lesions has been uncommonly reported, probably due to the low incidence of significant infrarenal aortic lesions. However, a review of the literature revealed that angioplasty of the infrarenal aorta has been described in about 280 patients and appears to be safe treatment with good primary (85%) and secondary (90%) patency rates during a mean follow up ranging between 4 and 52 months (24).

Stent Placement

Indications for stent placement in the pelvis include long segment disease, chronic occlusion, or focal lesions which demonstrate a suboptimal response to balloon dilatation. Many practitioners have a low threshold for stent placement, and perform balloon angioplasty alone only for category 1 lesions, which are those <3cm in length, concentric, and not calcified. Others even have proposed not performing balloon angioplasty without stent placement in iliac arteries. Stents do seem to improve upon the results of iliac angioplasty without increasing the complication rate seen in association with this procedure. Bosch et al. reported a 4-year success rate for iliac angioplasty of 44-65%, which, which increased to 53-

77%, after stent placement (25). Murphy et al. placed stents in 90 iliac arteries in 65 patients with claudication and found 1-year, 2-year, 3-year, and 4-year cumulative patency rates to be 77%, 71%, 62%, and 62% respectively (26). Lee, et al. reported 1-year, 2-year, and 3-year primary patency rates for stents placed in both the common and external iliac arteries. In the common iliac artery, these were 93%, 91%, and 90% respectively while in the external iliac artery, the primary patency rates were 88%, 85%, and 78% respectively (27). This is in contrast to the findings of Powell, et al who determined that patients with multisegmental disease without severe external iliac artery occlusive disease have acceptable patency after angioplasty and selective stent therapy but require frequent reintervention (28). The 3-year primary and primary-assisted patency rates in this study were 54% and 85% respectively. In patients with severe external iliac artery disease, the 2-year primary patency rate was 45% despite frequent reinterventions.

The death of percutaneous balloon angioplasty for focal iliac artery stenoses, however, is premature. Cambria, et al reported their results on 141 consecutive patients and concluded that primary stent placement does not improve upon the results of angioplasty alone (29). They demonstrated 1-year, 2-year, and 3-year clinical patency rates of 67%, 60%, and 54% respectively with secondary clinical patency rates of 74%, 67%, AND 61%. Most investigators recommend balloon angioplasty for AA category 1 lesions, followed by placement of a stent if suboptimal angiographic or hemodynamic results are achieved. While the management of blue toe syndrome attributed to iliac atherosclerotic plaques has been controversial, some investigators have found success by treating these patients with metallic stents as well (30).

Primary stenting of significant atherosclerotic lesions of the infrarenal abdominal aorta has recently been reported by Nyman, et al (24). They reviewed the literature and found primary and secondary aortic patency rates of 92% and 98% respectively, with following up ranging from 3.6 to 19 months. Audet, et al treated 92 patients with short infrarenal aortic stenoses with PTA and stenting and found a 5-year and 10-year primary patency rate of 72% and secondary patency rates of 88% and 76% respectively (31).

When determining what places a patient at risk for stent failure, factors such as female sex, SFA occlusion, perioperative vascular complications, and hypercholesterolemia have been implicated in lower patency rates for iliac stents (32). Treiman, et al also analyzed risk factors for early stent failure and found no independent variable in predicting success (33). While it has been felt by some that stent location (common iliac artery vs. external iliac artery) may predict lower patency rates (28), this has not been a uniform finding (27).

V. Stent Selection

The Palmaz P308 stent (Cordis/Johnson & Johnson, Warren, NJ) was approved in 1991 and was the first stent to gain Food and Drug Administration (FDA) approval for use in the iliac arteries. The Wallstent (Boston Scientific, Natick, MA) gained approval in 1996. Both stents were approved for use after suboptimal angioplasty based on historical comparisons with angioplasty, or in the case of the Wallstent, with historical results with use of the Palmaz stent. Both stents were approved for use after suboptimal angioplasty based on historical comparisons with angioplasty, or in the case of the Wallstent, with historical results with use of the Palmaz stent. Until recently, there was no other device approved for marketing for use in the iliac arteries. Since 1996, the FDA has required randomized trial design and objective performance criteria before considering approval of devices to be labeled as intravascular stents. The SMART stent is the first stent to gain approval for marketing for use in the iliac arteries since 1996. Since the approval of the SMART stent, the balloon expandable Zilver stent (Cook, Bloomington, IN) has also been approved.

The Cordis SMART Stent CRISP-US Study led to approval of the SMART stent for marketing as an iliac artery stent (34). The study is a multicenter, randomized clinical trial comparing the SMART stent (Cordis) and the Wallstent. There were 203 patients with chronic limb ischemia and iliac artery stenoses in the study. The indication for stent placement was suboptimal angioplasty results, with suboptimal angioplasty defined as 30% residual stenosis, flow-limiting dissection greater that the initial lesion length, or mean transstenotic pressure gradient of 5 mm Hg. Only two thirds of patients had mean pressure gradients greater than 5 mm Hg, which is usually considered the threshold for stent placement. The primary endpoint was a composite of 9-month restenosis, 30-day death, and 9-month target vessel revascularization. Secondary endpoints were (i) acute procedural success, (ii) early clinical success, (iii) late clinical success, (iv) hemodynamic success, (v) patency, and (vi) improvement in Walking Impairment Questionnaire scores. The study was designed as an equivalency study, and the primary endpoint was observed in similar numbers of patients at 9 months. Acute procedural success was significantly higher with the nitinol SMART stent, compared with the stainless steel Wallstent (98% versus 87%, respectively). Primary patency at 12 months was comparible (95% and 91%, respectively). On that ground, the SMART stent received FDA approval in September 2003 for improving lumen diameter in the iliac arteries.

There are several characteristics, which can be used to differentiate between the multitude of stents currently available. Hoop strength, the ability of a stent to withstand radial compressive forces, is a useful way to differentiate among balloon expandable stents due to the fact that these stents will be irreversibly deformed if the external loads exceeds their maximum hoop strength (34). The Perflex and the large Palmaz stent all had lower hoop strength values in this study.

For self-expanding stents, characteristics which are useful when comparing available stents include the chronic outward force and the radial resistive force. The chronic outward force is the measure of the force the stent exerts on the artery as it tries to expand to its nominal diameter. The radial resistive force is a measure of the force the stent exerts as it resists being squeezed by the artery. Among the nitinol stents, Duda, et al found the SMART Stent had a higher radial resistive force and chronic outward force than both the Memotherm stent and the Symphony stent (34). The Wallstent had lower values for radial resistive force and chronic outward force than all of the tested nitinol stents. These results are different from those obtained by Dyet, et al, who found that the Wallstent actually had more radial strength than the Vascucoil, Symphony, and Memotherm stents (36). This was measured by determining the force required to produce a 50% reduction in stent diameter.

The prototypical balloon expandable stent is the Palmaz stent. This is rigid with high hoop strength. When deployed, this stent rarely demonstrates any elastic recoil. It is therefore advantageous in focal, calcified or eccentric stenoses. It is also useful for ostial stenoses, as it maintains its rigidity throughout the stent, even at its ends. The Palmaz stent is the preferred stent for rigid or ostial stenoses. The Wallstent is the prototypical self-expanding stent. It is occasionally beset by elastic recoil. This is particularly prominent if the stent is used for an ostial lesion. In this situation, the stent must be positioned so that the lesion supported by one if the ends of the stent. The Wallstent, due to its flexibility and ability to conform to the course of the native artery, is the most desirable for diffuse or long segment stenoses or occlusions.

Covered stents are composite devices consisting of a metallic skeleton covered with synthetic graft material. Because of the bulky graft material, these devices require larger delivery systems. They are currently not FDA approved for use in iliac occlusive disease. Nevertheless, covered stents have been used in the iliac arteries, mainly for the treatment of aneurysms but also for arterial ruptures or arteriovenous fistulas. The most common devices are the Jostent Stent Graft (Abbott Vascular, Abbott Park, IL), the Wallgraft (Boston Scientific/Meditech, Newton, MA), and the Vibahn Stent Graft (W.L. Gore, Flagstaff, AR).

VI. Technical Considerations

Aortic Bifurcation Stenting

For bilateral, iliac artery stenoses and/or occlusions, or stenosis of the terminal aorta, it is usually desirable to deploy two stents simultaneously in each common iliac artery, extending from the common iliac arteries into the aorta as is required to cover the stenoses (“kissing stents”). The rationale for this is that placement of a single stent in the aortoiliac segment can potentially exclude the contralateral common iliac artery. In addition, the proximal end of the stent can be compromised if it abuts the contralateral aortic wall (37). While this technique is routinely utilized and its success has been described (38), it has been postulated that the protrusion of a stent into the aorta can alter the dynamics of flow, significantly contributing to accelerated formulation of myointimal hyperplasia, which can subsequently lead to stent thrombosis and failure (37).

Predeployment Angioplasty

Chronic occlusions are usually best managed by primary stent placement. Angioplasty prior to stent placement usually does not achieve a satisfactory result, and in fact may increase the chances of the patient experiencing complications from the procedure (39). However, it is unclear that stent placement for focal concentric, non-calcified stenoses (AHA category I) in the iliac artery provides any immediate or long-term benefit compared with balloon angioplasty. The cost of the stent is significant, and therefore, most practioners perform balloon angioplasty alone for focal iliac artery stenoses less than 3 cm in length, not calcified, and concentric (ie. TASC A and B lesions). In this situation, stent placement follows balloon angioplasty if hemodynamics indicate an unsatisfactory results, particularly if a flow-limiting dissection is present. However, when compared to primary stenting, selective stenting after failed/sub-optimal angioplasty has recently been shown to be inferior in treating TASC C and D lesions (40).

Endpoints for the Procedure

The endpoint for the procedure should e based on hemodynamics, which have been shown to be more accurate than angiography for this purpose (1). Ideally simultaneous waveforms obtained above and below the treated segment should overlap, with no mean or systolic gradient. Practically, most patients will have some separation of the waveforms at peak systole, with a slightly more rounded peak measured distally. The systolic gradient usually measures 1-3 mm Hg, but the mean gradient may still be zero. This is still an acceptable result.

Often, ideal results will not be achieved either due to recoil, the presence of mural calcification which prohibits adequate dilatation, or pain with inflation which precludes sufficient dilatation. Because pain is indicative of severe adventitial stretching, and may herald arterial rupture, it is desirable to not have patients heavily sedated during the balloon inflation portion of the procedure. It is important to slowly increase the atmospheric pressure during balloon inflation to correlate with the patient's pain tolerance. If severe pain is experienced, it is prudent to discontinue balloon inflation, or to switch to a smaller balloon and accept a less than perfect result due to elastic recoil in some locations within the stented artery. An alternative to high-pressure inflation or using a larger angioplasty balloon for a focal area of elastic recoil is placement of a short stent to prop this area open.

The patient treated for intermittent claudication will require a more perfect hemodynamic result than one treated for ischemia at rest, so those symptoms do not occur during exercise. Injection of vasodilators to assess results of an intervention can be informative when the results are borderline in patients with intermittent claudication. This mimics the physiology of increased demand for blood flow across the treatment segment, which is observed during exercise. A gradient of less than 8-10 mm Hg (mean) following the intraarterial injection of 200 micrograms of nitroglycerin is considered a satisfactory results, but the endpoint for patients with intermittent claudication should be as minimal a gradient as possible without undue risk.

VII. Complications and their Management

Local Complications

The most frequently observed complications of aortoiliac stent placement are local, and usually related to femoral artery access. Hemorrhage from the access site can cause a groin hematoma, or more ominously, retroperitoneal, properitoneal, or intraperitoneal hemorrhage. The incidence of such hematomas is more common than is seen in patients who undergo diagnostic arteriography due to the larger sheath size and the use of anticoagulants. Although local in origin, intraabdominal hemorrhage can results in systemic complications such as myocardial ischemia and infarction, acute tubular necrosis, and death. Patients who complain of "back pain" following the procedure should be viewed with concern. Any suspicion of hemorrhage would prompt a pelvic CT scan, typing and cross matching of blood, baseline hemoglobin and hematocrit levels, and secure IV access. Patients who do experience significant hemorrhage typically require surgery to repair the arteriotomy.

Other local complications, such as groin infection, are uncommon and usually respond to antibiotics. Guidewires and catheters can result in dissection and/or vessel occlusion. With stents, most of these can be managed percutaneously with some added expense and time, but without additional requirements for access and with little added risk to the patient.

Distal Embolization

Distal embolization is occasionally seen after iliac angioplasty and stent placement. When emboli lodge in the calf vessels, additional treatment may not be required if one or two other vessels are patent. If there is no continuous calf runoff due to an embolus in a calf vessel, the patient should be anticoagulated and antegrade access can be performed in conjunction with a previously placed retrograde access. Larger emboli, such as those in the profunda femoris or common femoral arteries, will often require surgical management. Thrombolytic therapy may be attempted depending on the viability of the leg, but emboli often contain plaque, which is not amenable to lysis.

Arterial Rupture

Arterial rupture has been uncommon in balloon angioplasty literature, but may occur in up to 1% of patients undergoing iliac artery stent placement. This is probably due to the severity of the disease in the arteries that are now being treated with stents. Rupture of an iliac artery or the aorta will result in hemorrhage in the retroperitoneum and/or pelvis, which is often accompanied by immediate hemodynamic compromise. The first sign of recognition that this has occurred may be pain upon balloon dilatation that persists after balloon deflation. Hypotension may be related to a vagal reaction and can be accompanied by bradycardia. Tamponading the bleeding with an angioplasty or occlusion balloon, infusing fluids, and preparing blood products are the first steps to take when this situation is encountered. Atropine may be used to reverse bradycardia if present. Fortunately, the immediate hypotension, which is often observed, is not due to volume depletion but appears to be a physicological response. This is usually short-lived. Following tamponade of the rupture site, plans can be made for surgical treatment or retrieval of a stent-graft if percutaneous management of this complication is being considered.

Stent Infection

Stent infection has been reported in increasing numbers during the last several years (41-46). This usually presents with a 10-14 days of stent placement and likely represents seeding of stents by skin flora at the time placement, especially during long or repeated percutaneous access (47). Using a swine model, Thibodeaux, et al (48) and Hearn, et al (49) found a 70% infection rate of iliac stents when given a S. Aureus challenge at the time of stent deployment and a 50% infection rate when the challenge occurs 28 days following deployment. The clinical manifestations of stent infection include fever, leukocytosis (predominance of polymorphonuclear leukocytes and immature PMNs), bacteremia with positive blood cultures, hemodynamic instability, localized pain and/or mass, petechiae in the affected extremity (due to septic emboli), and sometimes loss of pulse with ischemic symptoms. When septic arthritis is caused artery and surrounding soft tissues by virulent pathogens such as Staphylococcus Aureus, prompt surgical debridement of the artery and surrounding soft tissues with extraanatomic revascularization is mandatory. If patients are not managed promptly, septic morbidity, limb loss, and death may result. Therefore, conservative management is not an option although arteritis attributed to less virulent pathogens such as Staph. Epidermis have been managed successfully with long-term antibiotic therapy. Given the devastating consequences of infection, some have advocated the use of antibiotic prophylaxis (47) although a consensus opinion regarding prophylaxis has not yet been reached.

As can be seen, some of these complications are severe and life threatening. It is imperative that the physician performing the procedure be aware of the possible complications, and follow patients properly so that complications may be addressed promptly by the person most experienced in their nature and incidence. It is undesirable to be informed of a complication by the referring physician.

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