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Abdominal *into* Aortic
Aneurysms
Endovascular *and* Repair



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FOREWORD

Aneurysmal degeneration of the aorta is a frequent and often lethal process. In the Western countries abdominal aortic aneurysm (AAA) is still responsible for almost 1% of all deaths. The expected increase of people aged >65 years from 15% to 26% in 2040 will inevitably lead to an increase in AAA prevalence. Currently, treatment of AAA with endovascular (EVAR) or open means is a major part of the daily routine of most vascular surgeons and interventional radiologists in high volume centers.

It is of utmost importance that physicians who take care of patients suffering from AAA are well informed about the entire spectrum of this disease. In this book the current knowledge concerning the prevention and possible treatment strategies to slow down aneurysmal degeneration of the aortic wall has been gathered. Fundamental research combining sophisticated imaging techniques and the use of biobanks with search for (aortic wall and plasma) biomarkers, proteomics and genomes will be key factors for success. Because AAA cannot be prevented yet, screening for AAA seems valuable for several patient groups at risk, which is reviewed by the group of Powell.

Endovascular aortic aneurysm repair (EVAR) has gained widespread use during last decade. EVAR has lowered short-term morbidity and mortality, but is related to increased risk for reinterventions during follow-up. Key for successful EVAR is careful preoperative planning and sizing, with use of computed tomography (CT) scanning and center lumen line reconstructions. An overview of the newest generation endografts is part of this book and possible advances mainly in the proximal fixation technique will be reviewed. Despite all the innovations, follow-up post-EVAR is still mandatory. Recommendations concerning follow-up have been reviewed in the chapter by Wisselink *et al.* Last but not least it is important to overcome EVAR-related complications. Less invasive techniques to treat all kind of endoleaks are available nowadays and must be part of the armamentarium of the interventionalist who performs EVAR.

We sincerely hope a careful overview has been given concerning the entire spectrum of AAA disease and this book will help the physician to optimize taking care of a patient with an AAA.

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CHAPTER

6

Tips and tricks for successful EVAR

J. C. van den Berg

6.1 INTRODUCTION

Endovascular repair of thoracic and abdominal aortic aneurysms ((T)EVAR) has been increasingly used over the last decade. One of the major concerns in patients treated with EVAR is radiation exposure (and its potential long-term deleterious effects) and the use of iodinated contrast medium (that may affect renal function negatively, especially in this patient category that oftentimes is old and suffering from various comorbidities). The repeated frequent contrast exposure has been implicated in chronic oxidative renal injury, contributing to a steady decline in renal function.¹ A substantial amount of the radiation exposure and contrast dose is related to the endovascular procedure itself (apart from the exposure related to pre-operative evaluation and postprocedural follow-up).² It is of utmost importance to limit both radiation exposure and contrast dose to the absolute minimum, in order to reduce the morbidity related with contrast and radiation. Another important requirement for successful endovascular aortic or iliac aneurysm repair is the presence of an adequate distal landing zone in the common iliac artery. Aneurysmal aortas are associated with dilated common iliac arteries in about 20% of patients,³ making patients ineligible for standard endovascular repair. Because of the limit of a maximum diameter of commercially available iliac limbs, patients with large diameter common iliac arteries do not have a sufficient landing zone and therefore require extension of the stent-graft into the external iliac artery, with embolization of the internal iliac artery in order to prevent retrograde flow into the aneurysm from the hypogastric artery and thus a type 2 endoleak. In some patients both the internal and external iliac artery can be preserved by use of an iliac branched endograft. Although larger (aortic) cuffs can be used (bell-bottom technique), a larger than 22 mm diameter of the common iliac artery is considered to be a diseased landing zone,

prone to further dilation and a potential source of subsequent type 1 endoleak. Furthermore the presence of mural thrombus within the dilated common iliac artery may increase the risk of distal thromboembolism.⁴

Access problems may limit successful outcome, despite the use of lower profile delivery systems with improved trackability and extra-stiff guidewires that allows endovascular aneurysm repair (EVAR) in patients with tortuous iliac arteries. This is especially the case in patients with stenotic and calcified iliac arteries. Access problems are still common with an incidence reported as high as 7.7%.⁵ These difficulties are more likely to occur in patients undergoing thoracic (larger diameter delivery systems) or fenestrated (rotational movement required) stent-grafts. Access-related complications are a significant cause of morbidity and mortality in patients undergoing EVAR, and remain the principal cause of conversion to open aneurysm repair.⁶ Recent data suggest the rate of iliac artery/aortic rupture and arterial dissection remains around 1%.⁵

In this chapter tips and tricks to reduce both radiation exposure and contrast dose during the placement of thoracic and abdominal stent-grafts will be given, by using pre-procedural imaging and alternative techniques to identify key anatomical features. The technique and role of hypogastric artery embolization will be discussed, and finally ways to deal with difficult access will be dealt with.

6.2 PREPROCEDURAL PLANNING

Preprocedural planning is mainly used for sizing purposes (see chapter 4, van Herwaarden), but a lot of the anatomical information obtained with the computed tomography (CT) scan can be of help in facilitating the EVAR procedure, therewith reducing procedure and total fluoroscopic time.

The level of the renal arteries can be identified and easily related to the corresponding level of the lumbar vertebral bodies. This is most easily done by scrolling through the coronal and sagittal multiplanar reconstructions (MPR). Identification of the first lumbar vertebra is most easily done by observing the level of the lowermost rib (corresponding to Th12), or by counting backwards from L5 (this can also be done during the EVAR procedure, with the use of fluoroscopy). The position of the renal artery is usually at the L1-L2 level. With this information in mind the C-arm should be centered at the known level of the renal arteries by use of centering on the corresponding height with respect to the vertebral bodies (centering is of importance in order to reduce the so-called parallax error). This should be done after the main body delivery system has been inserted (and fluoroscopy is used to monitor the advancement of the delivery system in the iliac arteries [Figure 6-1]).

In a similar way the optimal angulation of the C-arm for visualization of the aortic arch and projection of the “full” proximal neck of abdominal aortic aneurysms in case of angulation of the neck can be chosen (Figure 6-2). The angulation can be determined best on sagittal MPR images, by calculating the angle between the longitudinal axis of the patient and the line perpendicular to the centre luminal line. This avoids trial and error movements of the C-arm in an attempt to find the optimal projection during the endovascular procedure.

By using this knowledge the number of angiographic runs can be reduced significantly. Another way to reduce this number is the simple measure of not performing any angiogra-

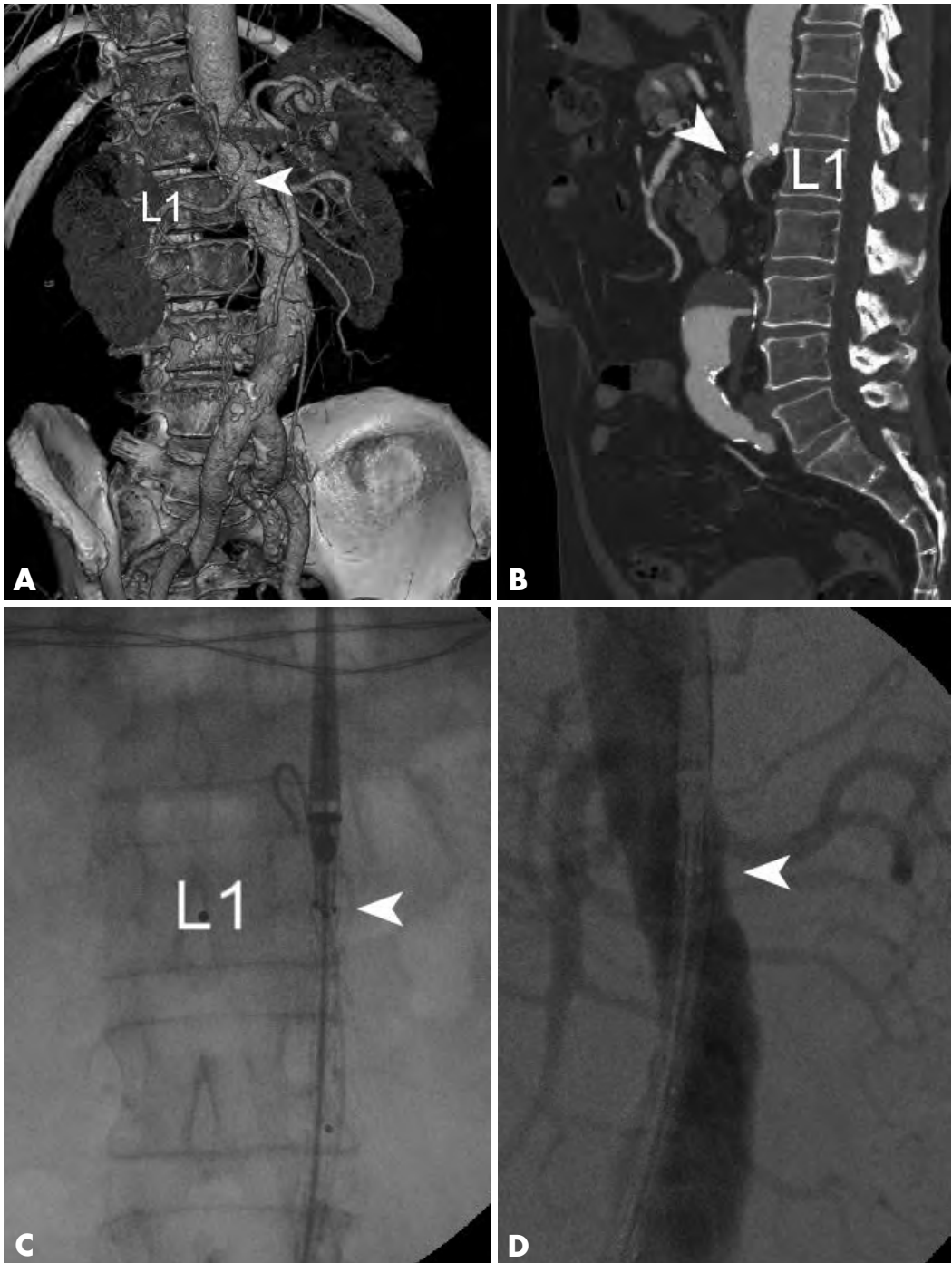
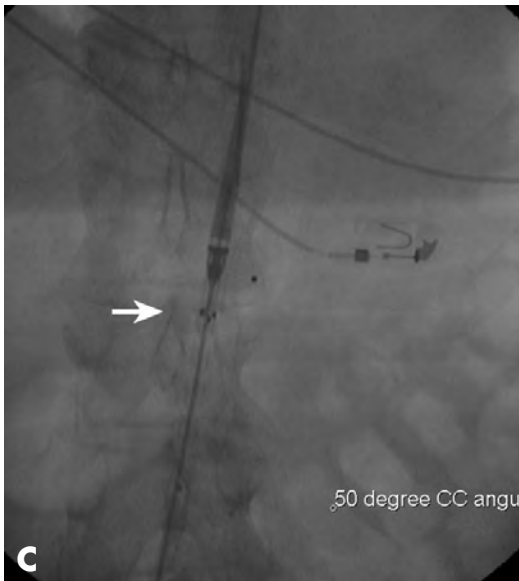


FIGURE 6-1. VRT reconstruction (A) and sagittal MPR (B) of CT scan indicating right renal artery (arrowhead); on both images the level of the renal artery relative to the vertebral body of L1 can be easily discerned; during EVAR procedure the C-arm is centered over vertebral body L1, and the stent-graft (arrowhead indicates proximal end of stent-graft) advanced until the level where the renal artery is anticipated (C); angiography (D) demonstrates near optimal positioning, only minor adjustments are needed.



FIGURE 6-2. Sagittal MPR of CT angiography (A), indicating the angle between the line perpendicular to the central axis of the proximal aortic neck, and the line indicating the AP projection axis; in order to project the proximal neck optimally during the EVAR procedure a 50 degree cranio-caudad orientation of the C-arm is required; MIP reconstruction of CT angiography (B), in a pure AP projection the proximal neck (distance between arrowheads) appears shorter than the actual length; fluoroscopic image (C) with 50 degree angulation of the C-arm during EVAR shows stent-graft (arrow); with this angulation the full length of the proximal neck (between arrowheads) is visualized during angiography (D).



phy prior to insertion of the main body of the stent-graft (keeping in mind that with a recent CT angiography at hand there is no need for a diagnostic angiography prior to stent-graft insertion). Since the combined rigidity of guide wire and the stent-graft delivery system tends



FIGURE 6-3. VRT image (A), and coronal MPR (B) of CT angiography demonstrating severe angulation (with kinking, arrowhead) of the proximal infrarenal aorta in a patient with distal migration of a previously implanted stentgraft; angiography during EVAR procedure (diagnostic catheter from a left femoral access, stiff guidewire from a right femoral access [C]) shows reduction of kinking (arrowhead), but bulging of the proximal neck towards the right is still present (arrow); angiography after insertion of the stent-graft (proximal extension) delivery system (D) demonstrates further reduction of kinking (arrowhead), and absence of bulging (arrow).

to ‘stretch out’ the vessels, the anatomical representation of the aorta and its side branches will be significantly different from the situation where only a diagnostic angiographic catheter is in place (Figure 6-3).

6.3 ALTERNATIVE TECHNIQUES TO IDENTIFY KEY ANATOMICAL LANDMARKS

In the vascular territories below the diaphragm CO₂-angiography can be used, and can help in identifying the level of the renal arteries. When using CO₂ as contrast agent, special software for the angiography system is needed, and some features of the angiography system cannot be used (*e.g.* road map). Therefore it will never be possible to completely eliminate the use of iodinated contrast medium during a procedure. No special equipment for CO₂ contrast injection is necessary. As an alternative or as a supplement to CO₂-angiography, gadolinium has been proposed as contrast medium. Gadolinium has the same attenuation characteristics as iodine and therefore no special settings for the X-ray equipment are needed.⁷ Cases of renal insufficiency at high dose Gadolinium injection have been described, but no safety risks are known at low dosage schemes (<0.4 mmol/kg body weight).^{8,9}

The last technique that can be used to identify side branches is placement of a catheter selectively at the origin of the artery of interest. This technique allows for accurate placement of the stent-graft without or with little contrast medium, and can be used only when preoperative imaging has demonstrated that all anatomical requirements for EVAR have been met. The technique can be used for identification of the location of the renal arteries, hypogastric arteries, the celiac trunk, and the left subclavian artery. For identification of the renal arteries, only cannulation of the most caudal renal artery is necessary. The selective catheter (Cobra or Simmons shape) is inserted from the contralateral side (with respect to the access of the main body of the stent-graft [Figure 6-4]).

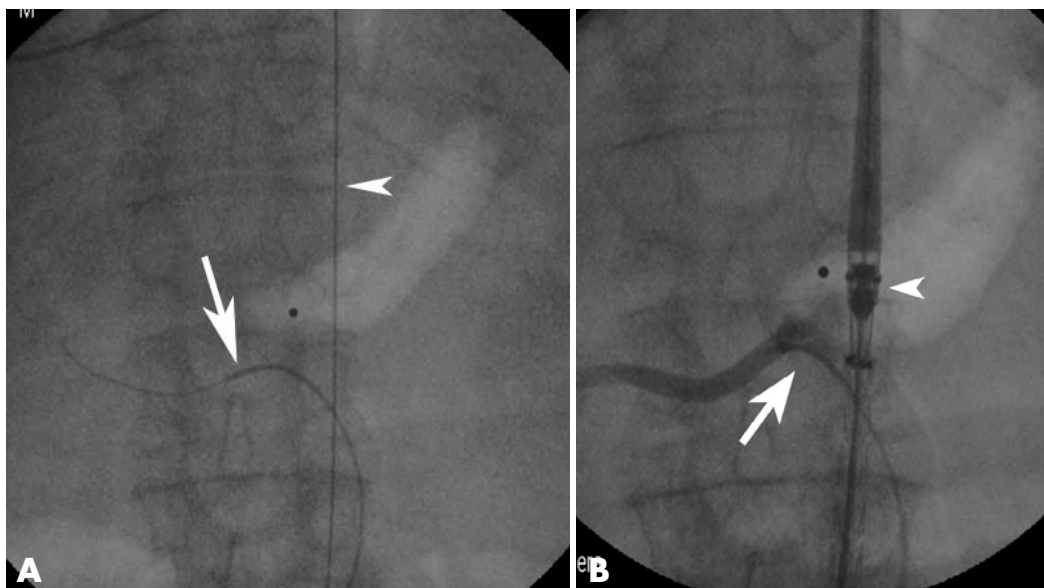


FIGURE 6-4. Fluoroscopic image during EVAR after selective placement of a diagnostic catheter (arrow in the right renal artery, stiff guidewire in place (arrowhead) (A); digital subtraction angiography after insertion of stent-graft delivery system (B) clearly demonstrates the lower margin of the ostium of the right renal artery (arrowhead), using a significantly reduced amount of contrast medium as compared to an abdominal aortography; similar images can be obtained by using CO₂ angiography or Gadolinium enhanced angiography.

This technique is especially helpful for identification of the level of the celiac axis in case of TEVAR. Angiographic identification of the celiac axis during TEVAR is hampered by the fact that it requires a (near) lateral projection, with resultant poor image quality, increase in radiation dose and problems in positioning the (mobile) C-arm (Figure 6-5).

In theory also the hypogastric arteries can be “marked” by the presence of a catheter or guidewire, but in practice this is not feasible since it requires insertion of a second (ipsilateral) sheath, that might impede advancement of the stent-graft delivery system, especially in narrow external iliac arteries.

Finally, in (rare) cases where an abdominal straight stent-graft (tube) is to be placed for a focal abdominal aortic aneurysm with sufficient distal neck, the distal aorta can be located by positioning a universal flush catheter in a “cross-over” position at the level of the aortic bifurcation. Likewise, this technique can be used for identification of the aortic bifurcation in cases of an isolated common iliac artery aneurysm, with sufficient proximal neck (Figure 6-6).

Additional advantage if the technique using catheter marking is that it allows for access to the sidebranch or cross-over access, in case of inadvertent too low or too high positioning of the (straight tube) stent-graft.

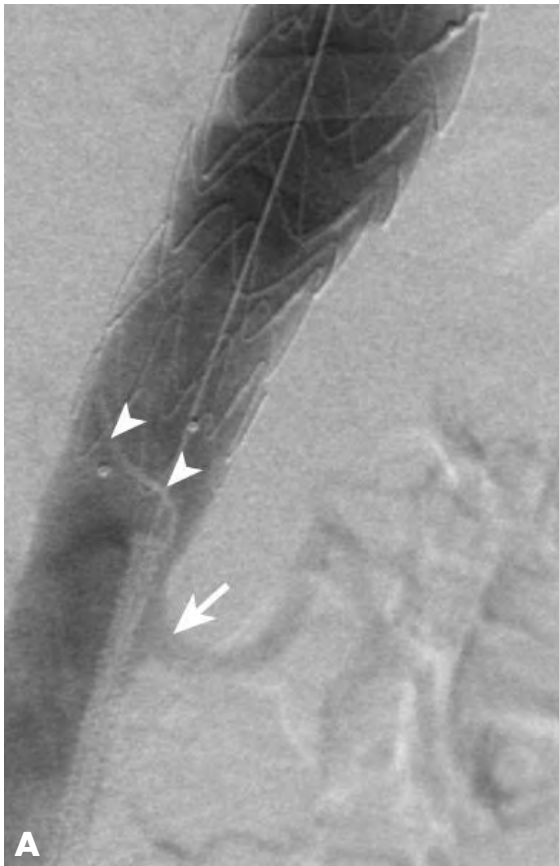


FIGURE 6-5. Digital subtraction angiography, with injection from a catheter in the proximal descending thoracic artery (brachial access [A]), after placement of a thoracic stent-graft; a Simmons-shaped catheter (arrowhead) that was used for location of the celiac axis is still in place, the left renal artery is indicated by an arrow; control CT angiography demonstrates patency of the celiac axis (arrowhead), with distal margin of (closed web) stent-graft just proximal to the celiac axis.

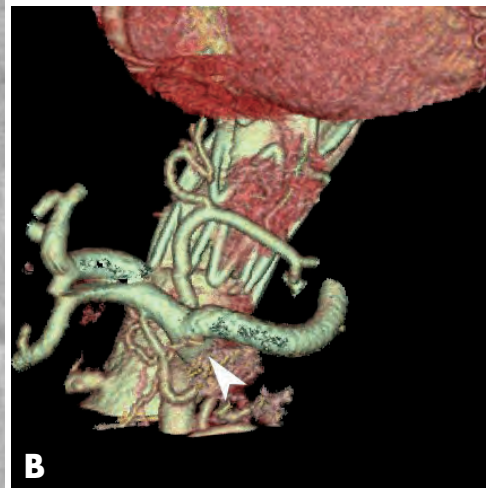




FIGURE 6-6. Coronal MPR of CT angiography (A) demonstrating penetrating ulcer of the infrarenal abdominal aorta; during EVAR with a straight stent-graft (B) the right renal artery and the aortic bifurcation are "marked" with a catheter (arrow) and guidewire (arrowheads) respectively; control angiography (C,D) demonstrates distal margin of stent-graft (arrow) and guidewire still in place (arrowheads).

6.4 TECHNIQUE OF HYPOGASTRIC ARTERY EMBOLISATION

Pre-treatment embolization usually involves occlusion of one or both hypogastric arteries, in order to be able to expand the anatomical inclusion criteria to perform endovascular treatment of aorto-iliac aneurysms extending up to or beyond the iliac bifurcation, preventing retrograde perfusion of the aneurysm sac. This is particularly true in patients where no iliac branched device can be implanted due to unfavorable anatomy. Indications for hypogastric artery occlusion are extension of the AAA into the common iliac artery with an insufficient distal neck, aneurysms involving the hypogastric artery and finally insufficient distal landing zone in the common iliac artery.¹⁰

In order to prevent retrograde flow into the aneurysm the most proximal non-aneurysmal part of the hypogastric artery should be occluded. It is of importance to occlude only the main trunk of the hypogastric artery, and leave the communication between the anterior and posterior branches of the hypogastric artery open. This approach will reduce the number of ischemic complications.¹¹⁻¹⁴ The relative risk of developing claudication after distal embolization in one series has been reported to be 4.6 times higher as compared to proximal embolization.¹⁰ Most interventionalists favor a staged procedure, performing the embolization prior to the EVAR, in order to reduce use of contrast material and operative time. Other reasons to perform a staged procedure are the lack of high quality fluoroscopy in the operative setting that may hamper navigation with microcatheters (with the advent of high-end hybrid operating rooms this is becoming less of an issue), and a local reimbursement system that favors outpatient embolization treatment. Finally there is an increased likelihood of developing transient buttock claudication when performing a concomitant, one-stage, procedure.¹⁵ Patients with impaired renal function are preferably treated with a staged procedure.

When both hypogastric arteries need to be occluded preoperatively, sequential bilateral embolization would reduce the risk of developing complications intuitively. It has been shown only in one study that simultaneous embolization of both hypogastric arteries can be performed with a complication rate comparable to that from other reports where a staged procedure was performed.¹² In these patients it is advocated to search for techniques to preserve at least 1 hypogastric artery like iliac branched device or surgical reimplantation of the origin of the hypogastric artery in the distal external iliac artery or external to internal iliac bypassing via retroperitoneal incision. Published series are however small, and to date it is not clear whether there are advantages of staged versus simultaneous embolisation, and controversy persists.

Coils should be oversized about 15-20% with respect to the target vessel in order to prevent distal migration of the device. Overly large coils will cause potential displacement of the catheter from its selected location.¹³ This is especially so when stainless steel coils (with a higher radial force) and platinum macro-coils are used. The lower radial force of platinum micro-coils allows adaptation of the coil even in cases of extreme oversizing (>50%), without the risk of catheter displacement.

Although coils can be placed using a selective diagnostic catheter (lumen 0.035"), use of a co-axial catheter system is preferable. Using the co-axial technique, the diagnostic catheter needs to have a lumen of 0.038", in order to allow for passage of a microcatheter. The most commonly used selective catheters are cobra-curved or Simmons-type catheters. The microcatheter should be inserted into the main catheter by means of a Y-connector, which allows for a continuous heparinized saline flush of the diagnostic catheter throughout the

procedure. The main advantage of using a co-axial system is the stability provided by the diagnostic catheter, allowing for movements of the microcatheter within the diagnostic catheter. These movements are needed for (some of) the packing techniques described hereafter.

The goal of embolization is to produce a permanent occlusion of the target vessel. Placement of coils in an elongated fashion will only provide temporary occlusion, and therefore it should be attempted to achieve a cross sectional coil occlusion with densely packed coils. Elongation of coils (either pushable or detachable) can be avoided by slowly retracting the microcatheter whilst moving back and forth its tip during deployment of the coil resulting in a weaving like pattern.¹⁶

When dealing with large diameter target vessels as the hypogastric artery, the risk of distal migration of the first coil beyond the main trunk bifurcation can be reduced by using the scaffold technique or the so-called anchor technique.

With the scaffold technique a stable matrix is formed either by deploying high radial force pushable coils or (preferably) detachable coils (with a complex, rather than helicoidal shape) first. Advantage of using detachable coils is the possibility to withdraw the coil in case of distal migration (usually caused by undersizing of the coil) and to correct coil position, or change diameter of the first coil to be placed. After creation of this scaffold (or endoskeleton or so-called nest), complete cross sectional occlusion is obtained by weaving smaller (fibred) coils into the remaining interstices as described above.

Alternatively, in cases where instability of the first coil is anticipated, the anchor technique can be used (specifically in the absence of detachable coils, Figure 6-7). With this technique the main catheter is placed in the target vessel to be occluded, and the microcatheter is advanced into a small side branch. Subsequently a (long) coil is placed for 1 cm to 2 cm in the side branch, the microcatheter is withdrawn and the rest of the coil is placed more proximally. Then complete packing is obtained by deploying multiple smaller coils.

As an alternative to coils a vascular occlusion device can be used.^{4, 17} The device should be oversized 30% to 50% with respect to the target vessel diameter. The vascular occlusion plug can be placed using either a long introducer sheath (compatible with the crossing profile of the plug) or a guiding catheter. When using the latter approach the size of the guiding catheter needed results in the use of a system with an outer diameter at least 2F larger as compared to when a sheath only is used. From a contralateral retrograde approach with cross-over technique a selective catheterization of the main trunk of the target hypogastric artery is performed. A (stiff) 0.035" hydrophilic guide wire is placed, and a standard exchange is made for the long introduction sheath (or alternatively guiding catheter). The tip of the sheath is positioned slightly beyond the level where placement of the vascular occlusion plug is planned. The dilator and guide wire are then removed and the plug is loaded according to the manufacturer's instructions for use. The plug can then be advanced using the delivery cable

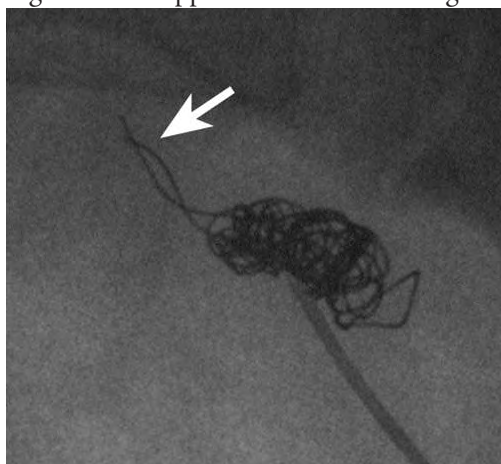


FIGURE 6-7. Fluoroscopic image during left hypogastric artery embolization demonstrating 2 coil segments protruding into small sidebranch; the coil "nest" is thus kept in place at the level of the main trunk.

until the desired position is reached (the plug being still within the sheath). Deployment of the plug is then achieved by withdrawal of the sheath. Control angiography is performed through the sheath to check for adequate position of the occlusion device (Figure 6-8). The plug can be repositioned if necessary, by pulling it back into the sheath, repositioning the sheath and redeployment. Once an adequate position has been obtained, release of the plug is achieved by rotating the delivery cable in a counter clockwise direction. As compared to coils, the AVP1 and AVP2 plugs require a larger sheath (potentially leading to more access site complications). Advantage however is that the plug can be placed as proximal as possible.¹⁸



FIGURE 6-8. Selective angiography (A) of the right hypogastric artery in a patient with an isolated common iliac artery aneurysm extending to the level of the iliac bifurcation, from a contralateral approach using a 6F long sheath (arrowhead), clearly demonstrating the main trunk of the hypogastric artery (arrow); control angiography (B) after vascular plug (arrowheads) placement demonstrates absence of flow; angiography during placement of iliac stent-graft (C) demonstrates aneurysm (arrow), during the procedure the level of the aortic bifurcation is “marked” by a universal flush catheter (arrowhead); control angiography (D) shows exclusion of the iliac aneurysm (arrowhead), and rapid filling of the distal branches of the right hypogastric artery (arrow) through collaterals from the left side.

After positioning of coils or vascular plug a control angiography is performed, and this should demonstrate absent or at least reduced flow into the hypogastric artery. Complete stasis of flow is not obligatory: the vessel will thrombose over time (after deployment of the stent-graft or during follow-up).^{13, 15}

In case bilateral embolization of the hypogastric artery is required, certain principles need to be followed in order to reduce complications. This includes embolization of the common trunk of the hypogastric artery, staging the procedures, preserving collateral branches from the external iliac and femoral arteries (femoral circumflex artery) and avoiding embolization when other collateral arteries to the pelvis and spinal cord may be compromised.¹⁹

The choice of embolic device and approach of embolic device are dictated by target vessel diameter and the tortuosity of the iliac arteries. A contralateral, cross-over, approach is most frequently used, and even large bore guiding catheters can usually be positioned at the origin of the hypogastric artery easily. The ipsilateral approach is feasible with the use of 4F and 5F diagnostic catheters (preferably Simmons/sidewinder shape), in combination with coils or the smaller vascular plugs. Very rarely it is impossible to cannulate the hypogastric artery.³

6.5 TECHNIQUE FOR DIFFICULT ILIAC ACCESS

Various techniques have been described to facilitate the introduction of aortic stent-grafts, and consist of both open and endovascular procedures. In patients with an isolated, short and focal iliac artery stenosis, simple balloon angioplasty may be successful (Figure 6-9).²⁰ In patients with diffusely stenotic and calcified arteries this technique is considered less helpful.²¹ The insertion of brachiofemoral wires can also be used in an attempt to straighten tortuous and diseased iliac arteries and further increase pushability and trackability.²² This technique requires additional brachial access and manipulation of catheters and wires in the aortic arch, which is associated with an increased risk of stroke. All the endovascular techniques described above do not prevent iliac artery rupture, which is a major concern when introducing a large diameter system through diffusely diseased and calcified iliac arteries. In patients with severe unilateral iliac disease, it may be preferable to place the main body from a contralateral approach (advancing the large bore main body delivery system at the side that is less diseased). As an alternative an aorto-uni-iliac stent can be performed, but this technique has the disadvantage of the necessity of performing a prosthetic femoro-femoral bypass graft. A hybrid technique using a retroperitoneal access can be used to help manipulate stent-grafts through the diseased iliac artery either through a direct approach or via a conduit sutured to the common iliac artery (or distal aorta in case of TEVAR). Retroperitoneal surgery will add significant morbidity to conventional EVAR.^{23, 24} Morbidity may be reduced by using laparoscopic surgical techniques.²⁵ In order to treat patients with diffuse stenoses, without converting to a hybrid approach (with its associated morbidity) the “paving and cracking” technique has been described.²¹ This technique can also be employed successfully in other situations, including iliac occlusions and ostial lesions, provided the lesion can be crossed with a guidewire. Patients with disease extending into the distal external iliac artery or common femoral artery may require an additional endarterectomy. After obtaining common femoral artery access (either percutaneously or open), a hydrophilic guidewire and catheter are passed across the iliac axis into the distal descending aorta. The hydrophilic guidewire is then exchanged for an extra-stiff guidewire. An attempt is then made to advance the stent-graft delivery system. If

the delivery system meets resistance, the delivery system should be removed, and subsequently arterial dilators and angioplasty are used, starting with large bore (<16F) sheaths and or dilators, with a long tapered nosecone. If after this procedure introduction of the aortic stent-graft is still impossible, balloon angioplasty is used and the common iliac artery is dilated to 8 to 10 mm and the external iliac artery to 6 to 8 mm. If these methods are unsuccessful, an aortic stent-graft delivery system can most probably not be safely introduced without a significant risk of dissection or rupture. The next step is then to reline and dilate (“paving and cracking”) the iliac arteries with covered stents. Both self-expanding and balloon-expandable PTFE-covered stents (Advanta V12 (Atrium Medical Corp, Hudson, NH, USA) or Fluency (C.R. Bard, Tempe, Arizona, USA)) can be used for this purpose. The covered stents are deployed along the length of the diseased iliac arteries, making sure to cover the hypogastric artery bifurcation, as this is typically the site of rupture (the hypogastric artery is usually severely stenosed in patients with such extensive disease). The covered stents are dilated to 9 to 10 mm in the external iliac artery and 10 to 12 mm in the common iliac artery. The covered stent prevents hemorrhage from the iliac rupture that is likely to follow such excessive dilation. Once the iliac artery has been relined and dilated, the main body of the aortic stent-graft can be inserted easily and deployed in the standard fashion. The iliac limbs of the aortic stent-graft should be extended into the covered stents in the iliac arteries to ensure seal.²¹

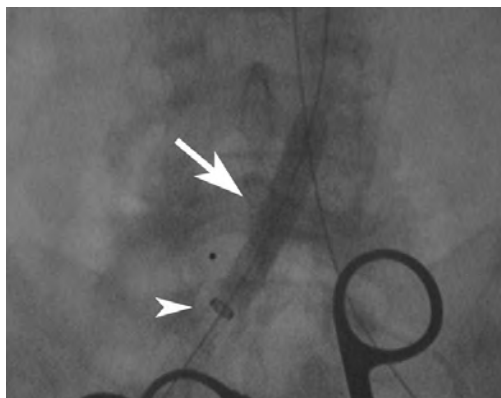


FIGURE 6-9. Fluoroscopic image obtained during EVAR in a patient with a severe stenosis of the proximal right common iliac artery; initial passage of the stent-graft delivery system, and subsequent crossing of a 18F long sheath was impossible; after extracting the dilator of the 18F sheath balloon angioplasty was performed (arrowhead indicates end of the sheath, arrow indicates PTA balloon); subsequent passage of the stent-graft delivery system was uneventful.

6.6 CONCLUSIONS

Several techniques exist to optimize stent-graft placement in EVAR and TEVAR procedures. With the use of knowledge obtained from preoperative imaging procedural length, contrast dosage and radiation exposure can be significantly reduced. Preoperative imaging will also allow for identification of access problems, and the need for pre-EVAR embolization of the hypogastric artery. By using embolization and other endovascular techniques the indication for EVAR can be expanded to patients with small or large iliac artery diameter, that otherwise could not be amenable to such a minimally invasive therapy without a significant morbidity.

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