Optimal Imaging for Endovascular Procedures: Redefining the Gold Standard

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Minimally invasive techniques have been gaining popularity in all fields of surgery. Their application to vascular surgery has spawned advances in endovascular treatment of aneurysmal and atherosclerotic arterial disease. These procedures are dependent on various imaging modalities, including angiography, intravascular ultrasound, and computerized tomography scanning to choose appropriate candidates and devices, and to assure precise endoluminal treatment. No single imaging method is adequate for all aspects of endovascular surgery; however, an algorithmic approach may judiciously reduce the inherent inaccuracy and morbidity associated with current methods.

INTRODUCTION

Endoluminal repair of vascular lesions is a subject of much worldwide research and debate. One area of concern regarding the use of these procedures is assuring appropriate pre-, intra- and post-procedural imaging for selection of candidates and guidance of interventions. In order to perform these "minimally invasive" techniques, proper endovascular candidate selection is required to ensure safe and successful deployment of devices.[1-3] Procedural imaging is likewise of paramount importance for determination of device sizing, identification of vascular anatomy, evaluation of procedural efficacy, and ultimately for accurate placement of devices.[4] Furthermore, post-procedural imaging is necessary to follow repairs objectively in order to assess long-term viability, and also to monitor for treatment failures such as early restenosis or inadequate sealing of excluded lesions.

As technology improves the devices and techniques, it has become clear that no single imaging method serves as the optimal modality in endovascular surgery. Angiography (A), computerized tomography (CT), magnetic resonance imaging (MRI), duplex and color flow ultrasound (US), and intravascular ultrasound (IVUS) each offer unique features which complement the deficiencies of other methods and provide a multi-modality approach to imaging in endovascular surgery. An algorithmic approach to currently available imaging is useful for optimal endovascular results. The following brief discussions of various current and developing endovascular therapies highlight the changes that are occurring and outline our imaging protocols that have evolved to assure effective device utilization.

BALLOON ANGIOPLASTY WITH STENTING

Atherosclerotic occlusive disease leading to significant hemodynamic compromise is the usual indication for balloon angioplasty. It is evident that intra-procedural imaging with uniplaner contrast angiography is inaccurate for estimation of post-balloon residual stenosis, and

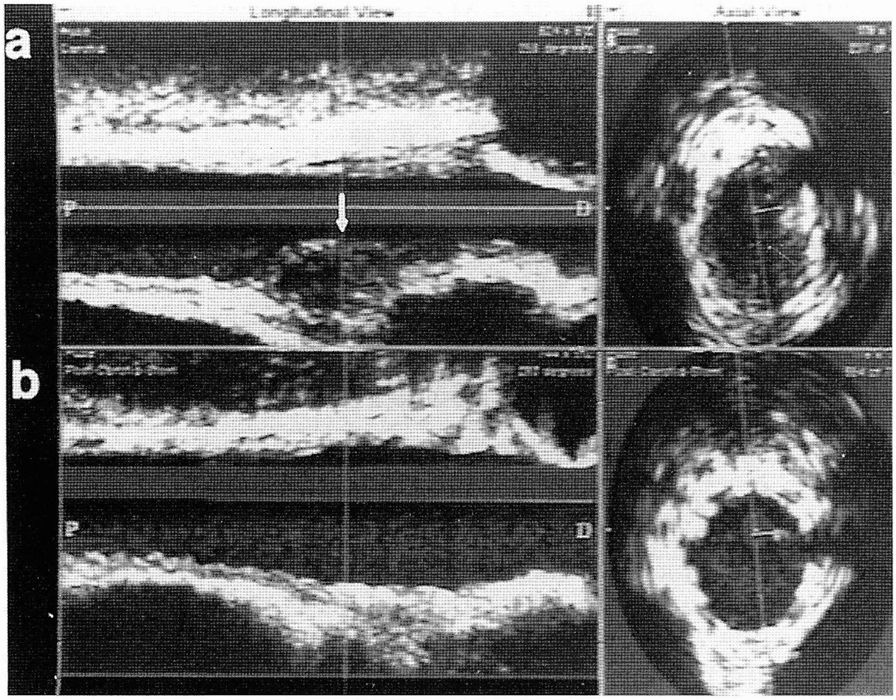


Figure 1. A series of axial IVUS images obtained of the carotid lesion (right) compared to the series of longitudinal gray scale reconstructions of the artery (left), following balloon angioplasty (a) and stenting (b). Arrow notes the site of residual 70% stenosis following balloon angioplasty. Note the dramatic volumetric change demonstrated by IVUS from the postdilation images compared to the poststent studies. The 140% volumetric change in luminal area measured by IVUS is substantially different than the 50% volumetric change estimated from angiographic images acquired at the same intervals. (With permission: J Endovasc Surg 1996;3:63-8.)

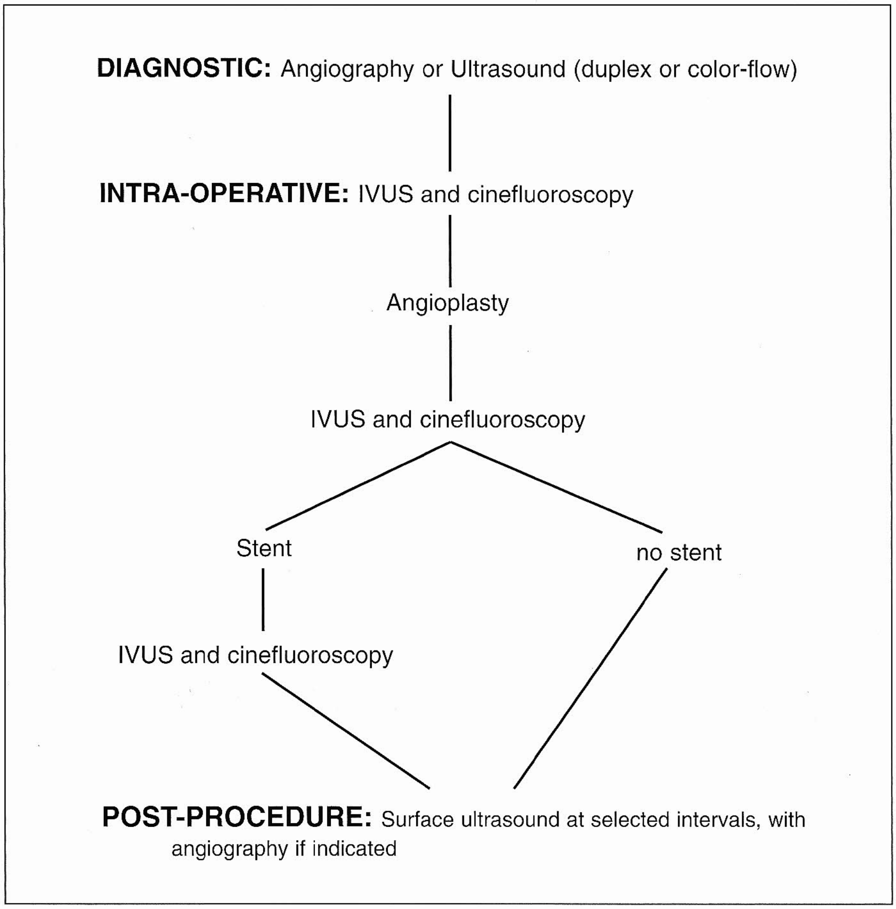


Figure 2. Imaging algorithm for balloon angioplasty and stent procedures.

therefore may underestimate the need to stent lesions which remain with significant stenoses.[4] Initial diagnosis is generally made using transcutaneous ultrasound, contrast angiography, or magnetic resonance angiography, depending on the arterial site and concomitant medical conditions such as renal insufficiency and contrast allergies. The addition of IVUS to the procedural imaging armamentarium in these cases affords a more accurate assessment of post-angioplasty stenosis and will help determine those patients in which a stent may be of value, based on evaluation of success of angioplasty, as well as identification of morphology and characteristics such as calcium which may benefit from stenting.[5] Hoyne et al.[6] described that IVUS identified calcium in 83% of atherosclerotic vessel walls while contrast angiography identified calcium in only 14% of the same arteries. These calcified vessels were more prone to dissection with angioplasty and yielded a larger lumen than fibrous lesions.

We recently published a report describing the importance of IVUS for determining the outcome of balloon angioplasty of a symptomatic carotid stenosis in a 68-year-old male.[7] The post-angioplasty contrast angiogram suggested an 80% lumen, while IVUS detected a residual 70% stenosis which was subsequently treated with stent placement. The post-stent cross sectional area determined by angiography was 110% compared to a reference segment of carotid artery, while IVUS showed that the area of the treated vessel was 170% compared to the same reference. Figure 1 compares the pre- and post-stent internal carotid as seen with IVUS. This case demonstrates the inaccuracy in quantifying angioplasty outcome using contrast angiography alone and illustrates the role of IVUS in assessment of critical determinants of success. This is particularly important in therapies like carotid angioplasty where quantitative information regarding initial outcome and recurrence phenomenon are paramount for determining utility compared to a known surgical standard. Figure 2 provides an algorithmic approach to imaging for angioplasty and stenting procedures for atherosclerotic disease.

ARTERIOVENOUS FISTULAE AND PSEUDOANEURYSM EXCLUSION

Traumatic arteriovenous fistulae and associated pseudoaneurysms, particularly in difficult-to-access areas such as the subclavian artery, or previous surgical fields

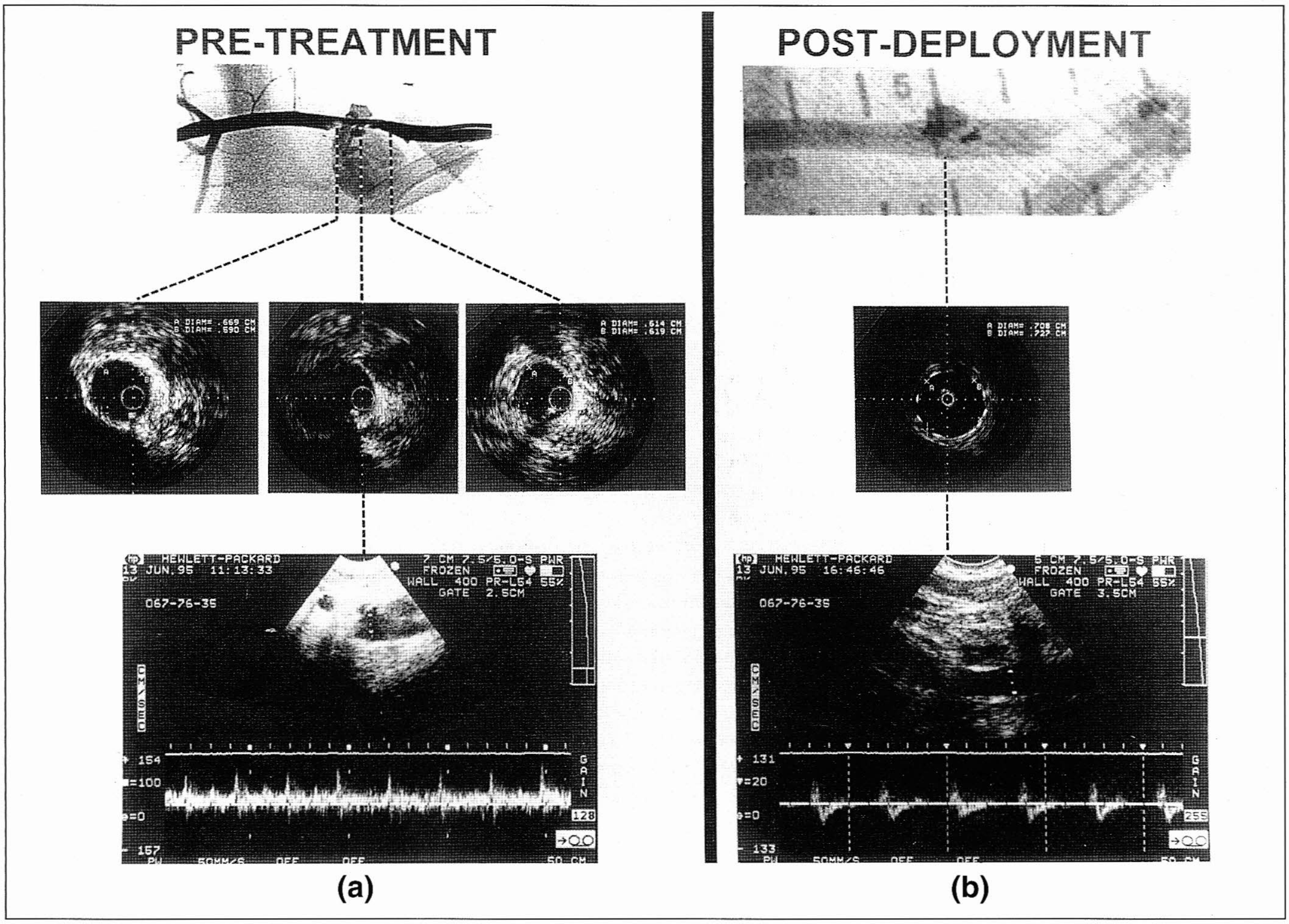


Figure 3. Composite photograph of the pre- and post-treatment images acquired during intravascular ultrasound guided deployment of an endoluminal graft to treat an arteriovenous fistula of the right axillary artery following gunshot injury. Intravascular ultrasound images acquired at the beginning of the procedure revealed dimensions of the proximal and distal artery, and the length of the injury to the vessel. A corresponding duplex surface gray-scale surface ultrasound image of the lesion prior to beginning the intervention demonstrates the arteriovenous connection. The post-deployment angiogram demonstrates the complete isolation and exclusion of the A-V fistula which is confirmed by the intravascular ultrasound inspection and post-procedure gray-scale duplex imaging of the device. (With permission: J Vasc Surg. In press.)

can be reached from remote sites such as the femoral and brachial arteries for endoluminal repair.[8-10] Preoperative imaging usually consists of angiography and/or US which are common methods by which the diagnosis is made. Figure 3a represents the axillary pseudoaneurysm of an 18-year-old male victim of a thoracic gun shot wound by both angiography and transcutaneous ultrasound. Once diagnosed, the patient was selected for an endovascular repair. A brachial artery access approach was used and IVUS instituted to document the length of affected subclavian artery in order to determine length of stent-graft necessary. An autologous cephalic vein graft was secured to a balloon expandable stent, and deployed across the arterial defect, thus excluding the pseudoaneurysm. Figure 3b shows the post-deployment angiograms and ultrasound. IVUS images before and after the stent-graft deployment, demonstrate patency of the stent along

DIAGNOSTIC: angiogram or ultrasound

INTRAOPERATIVE: IVUS

device deployment (± IVUS real-time)

Intravascular Ultrasound and contrast angiography

Post-Procedure: Ultrasound at selected intervals, angiogram if necessary

Figure 4. Imaging algorithm for endoluminal treatment of arteriovenous fistulae and pseudoaneurysm.

with successful exclusion of the pseudoaneurysm. Ultrasound can be used to determine long-term patency, stent diameter, continued absence of pseudoaneurysm flow, and persistent graft flow velocity.

The imaging algorithm for endoluminal repair of AV fistulae and pseudoaneurysm is demonstrated in Figure 4.

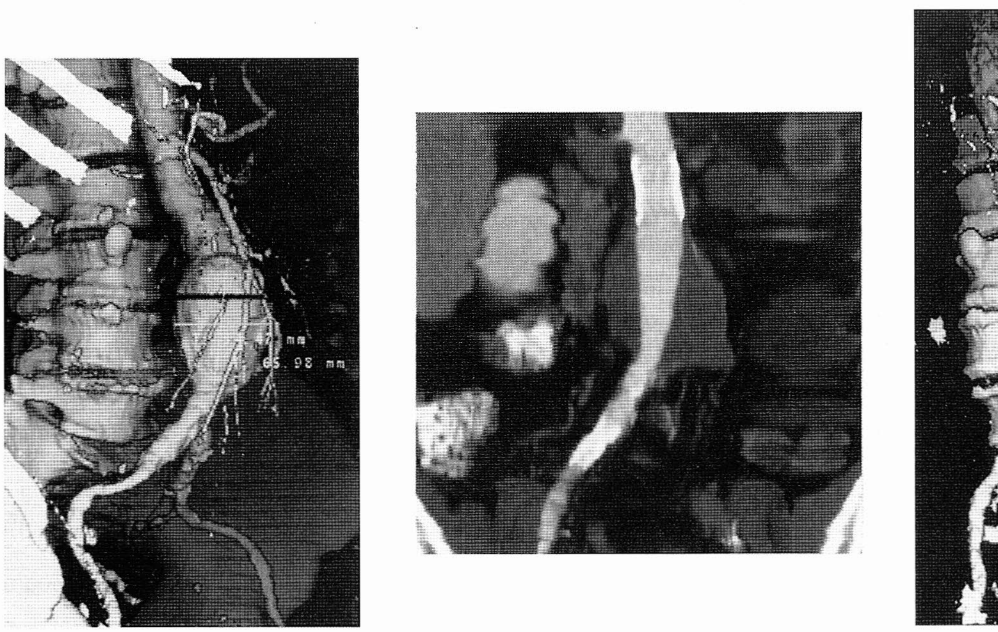
ENDOVASCULAR EXCLUSION FOR ANEURYSMAL DISEASE

Aneurysmal disease, either aortic or iliac artery in origin, is one of the more interesting applications of current endovascular stent-graft technology. Attempts have been made to exclude AAA via an endoluminal approach since 1976 in a canine model,[11] with Parodi reporting the first successful human AAA exclusion in 1991.[12] Aneurysm exclusion is also an area in which imaging is particularly crucial in the preprocedural patient selection.[13] Because many patients with aneurysmal disease suffer from other concomitant medical problems, minimizing the surgical insult is an appealing proposal. Unfortunately, from earlier work performed by Chuter[14,15] studying aortic anatomy, it became clear that only a select proportion of the patient population would have vascular configurations suitable for aorto-aortic tube grafts, which were the first type of exclusion devices placed. Tube grafts placed in patients without adequate proximal or distal stent fixation sites can develop endoleaks which continue to feed the aneurysmal sac; such endoleaks, which may continue with time, have a potential for rupture.[16]

Another area of anatomic concern is the iliac arteries which serve as the delivery conduit from a femoral insertion site,[17,18] and also as a distal anchor site in aorto-iliac[12,19] and bifurcated systems. Tortuosity and stenosis of these vessels may be excluding factors in patients depending on the delivery system design and size. Rupture of these vessels is a known complication of excessive interventional manipulation.[13] Dissection techniques for straightening the iliacs may be employed to reduce tortuosity and aid device delivery.

Selection of candidacy is also dependent on supra-aneurysmal anatomy. Accurate preoperative measurements of renal vessels, renal artery to aneurysm sac length, and diameter of proximal aorta all weigh heavily in the choice of appropriate patients and devices. For most available devices, a proximal neck greater than 1.5-2.0 cm in length is necessary for seating of the proximal portion of the stent-graft. Additionally, aortic diameters in excess of 24 mm are beyond the capabilities of current balloon expandable technology, and most self-expanded stent systems are limited as well beyond 28 mm, although devices of larger diameter are being developed.

CT scanning and ultrasound imaging remain the primary diagnostic tools in patients with abdominal aortic aneurysms (AAA). While physical examination remains an important screening tool, accurate dimensional assessment can be obtained by both CT and US. These tools also allow noninvasive follow-up in patients whose aneurysms may not be of caliber associated with spontaneous rupture risk, but in whom, the rate of growth and eventual size may warrant intervention. In patients referred for evaluation for endovascular aneurysm repair, CT scan is taken one step further to include spiral scan-derived three-dimensional (3-D) images. These reconstructed 3-D views allow measurement of aortic diameter and length, iliac anatomy including tortuosity and stenosis, and afford the best measures of preoperative candidacy currently available. In addition, this is a noninvasive imaging technique which can be performed quickly, with only the consideration of intravenous



(a) (b) (c)

Figure 5. Composite photograph of a spiral CT before intervention (a), with the corresponding longitudinal 2-D reconstruction (b), and 3-D spiral CT reconstruction of the aortoiliac exclusion of the aneurysm following the procedure (c). The longitudinal 2-D image demonstrated exclusion of the aneurysm (single arrow) by the endoluminal graft. The 3-D reconstruction following the procedure demonstrates no flow in the aneurysm sac with occlusion of the contralateral iliac artery by an endoluminal occluder (double arrows). The femoro-femoral reconstruction is not demonstrated on this photograph (with permission: J Vasc Surg. In press.).

contrast load perhaps excluding patients with renal insufficiency. In this case, MRI and MR angiography may substitute.[20]

Provided the patient has no history of distal arterial insufficiency such as claudication, rest pain, or non-healing ulcers, angiography is not a requirement of pre-interventional assessment, and adds no additional information. Figure 5a represents the preoperative spiral CT scan from a 72-year-old male with previous myocardial infarctions and end-stage renal disease on dialysis.[13] From this study, measurements were taken to determine candidacy, which was based on proximal neck length, diameter, and relative lack of iliac tortuosity. Construction of the endoluminal device was also based on this study. The aortoiliac design was chosen because of the short distal aortic neck. This design consists of a Palmaz Extra-large stent (Johnson and Johnson Interventional Systems, Warren, N.J.) sewn to the proximal end of a bifurcated 22-mm x 11-mm Cooley Veri-soft Graft (Meadox, Oakland, N.J.) from which the contralateral iliac limb had been amputated and oversewn.

A goal of endovascular techniques should be to minimize insult to the patient, including the use of contrast agents. Partially for this reason, IVUS is the primary intraoperative modality in conjunction with cinefluoroscopy for identification of renal vessels, reassessment of aortic anatomy, proximal neck length and diameter in comparison with preoperative CT scans, and site determination of common iliac seating for the distal end of this aorto-iliac system.[21] IVUS has been shown to be accurate for determinations of sizing as well as evaluating tissue composition of vessel walls.[22-24] Only minimal amounts of contrast agent are necessary during procedures, primarily for evaluating post-deployment graft flow continuity.[10,13] IVUS can also determine stent-graft apposition to aortic wall and may suggest further balloon dilatation for proper graft apposition.

As follow-up, 3-D reconstructed CT scans can be utilized to evaluate the success of the procedure. It is imperative that mid- and long-term follow-up be performed.[25] Aneurysm exclusion is based on the principle that aneurysms not subjected to arterial flow will not rupture, and diameter decreases in the aneurysm can be noted.[13,25] Figure 5b demonstrates the post-deployment CT scan and 3-D reconstruction of patient described above. Note the contralateral left iliac occluder necessary for this particular system design. There is no backflow through branch vessels into the aneurysmal sac, nor is there any evidence of endoleak. Not seen in this study is the femoral cross-over graft required for contralateral perfusion. This patient can be further followed with transcutaneous ultrasound for evaluation of aneurysm size and femoral-femoral graft patency at preselected intervals with the intent to identify areas of graft compromise and intervene before endoluminal graft failure. At present, this patient is asymptomatic. A proposed imaging algorithm is seen in Figure 6.

Para-anastomotic pseudoaneurysms of the aortic and iliac suture lines following bypass surgery for aneurysmal and occlusive disease can be imaged in similar fashion to primary aortic aneurysmal repair, as described previously. Endovascular treatment can be performed using isolated stent-graft placement across disrupted suture lines, as well as deployment of aorto-iliac systems for complete replacement.

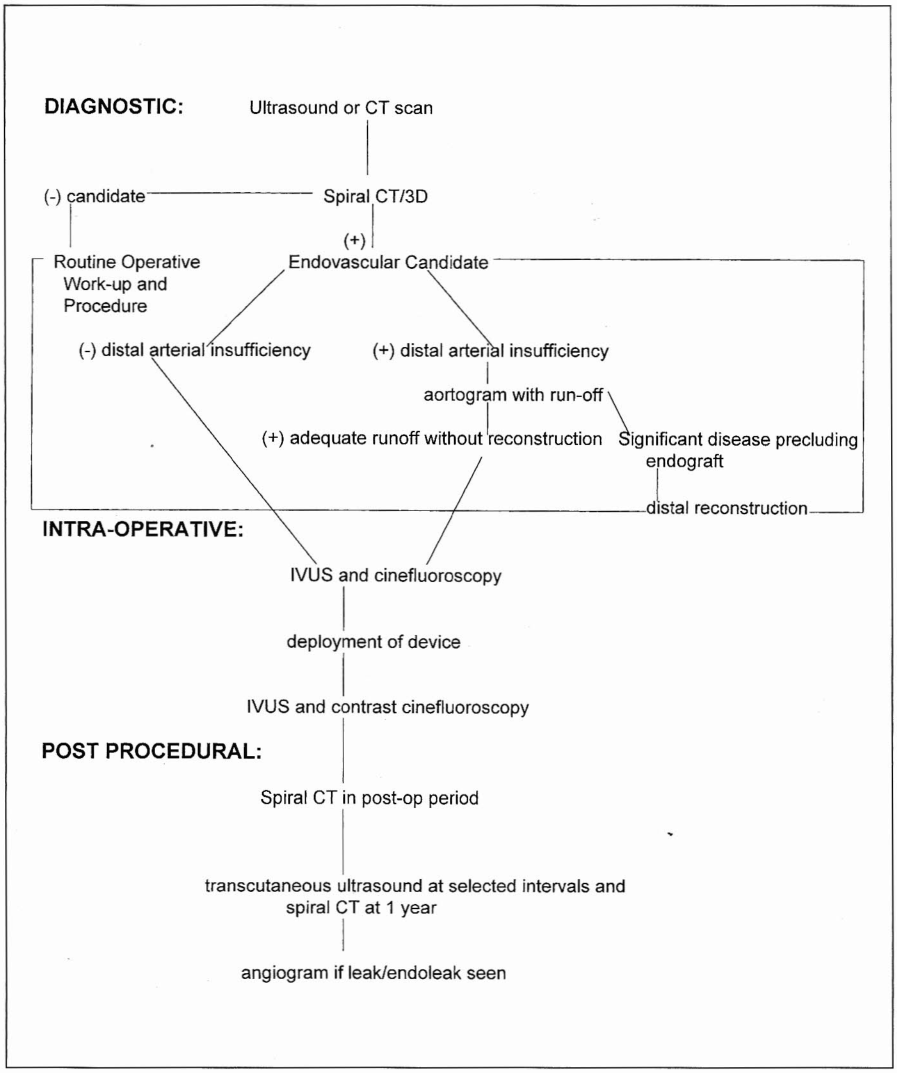


Figure 6. Imaging algorithm for endoluminal treatment of abdominal aortic and iliac aneurysms as well as para-anastamotic pseudoaneurysms. IVUS is used in conjunction with fluoroscopy to calibrate image level with bony landmarks and radiopaque markers placed on or beneath the patient.

DISCUSSION

Endoluminal treatment of traumatic, atherosclerotic, and aneurysmal arterial disease is an appealing alternative to the more traditional surgical methods. If a simpler and safer way to treat arterial disease can be performed with an improvement in morbidity and mortality for these patients, many of whom have high-risk medical conditions, a compelling reason to expedite developments exists.[3,25,26] As stent-graft design improves, and candidacy is broadened, preoperative evaluation becomes of paramount importance for evaluation of aortic anatomy. Aortic anatomy tortuosity and mural thrombus take on an important role, as these can lead to a misinterpretation of luminal length and therefore length of device.[13,27] Preoperative CT scan with or without angiograms is not ideal. 3-D reconstruction of spiral CT images more accurately represents luminal length and course, with the best representation of the vascular elongation which occurs in several planes.[2,14,15,27,28] Angiography does not add necessary information to the evaluation of candidates and imposes a procedure-related morbidity rate of 0.5-2.5% for local complication and a 2-44% intravenous contrast reaction, depending on use of ionic or non-ionic contrast and previous reaction to the dye.[29] Angiography is also inaccurate in comparison to CT scan for determining AAA size or evaluation of pseudoaneurysm, and would only be required if the patient has a history suggestive of distal ischemia. In patients with renal insufficiency, magnetic resonance angiography will reduce the amount of contrast needed, and may provide enough information to determine candidacy, with further evaluation necessary by IVUS during the procedure.[13,20]

During the procedure, IVUS, along with cinefluoroscopic guidance to calibrate images with bony landmarks or externally placed markers, can become the sole imaging modality, although some feel the addition of angiography makes the evaluation complete.[10,30] IVUS can determine vessel length, diameter, lesion morphology, dissection entry, and location of side branches such as the renal and infrarenal iliac arteries. IVUS also can expose incompletely seated stents which could lead to stenosis or peri-stent graft leaks.[31,32] IVUS can also delineate balloon angioplasty failures, and in those instances a stent may be used.[33] There is a high correlation between IVUS and postprocedural assessment in terms of lesion morphometric analysis.[22,34-36] Calcification can be superficial or incorporated within the media which may alter choice of therapy.[5,6,37] IVUS is therefore crucial in cases of stenting for occlusive disease.[38-40]

Success of endoluminal treatment for aneurysmal disease can be defined as complete exclusion of the aneurysm with restoration of normal blood flow, with the stent graft in proximal and distal contact with normal intima.[10-13] This can be confirmed at the time of deployment with IVUS and angiography, in the early postoperative period with CT scan (3-D if possible), MRI, or ultrasound. Evaluation through the early mid-term (6 months) and the late mid-term period (1 year), as well as long-term (3-5 years) follow-up can be performed with ultrasound or CT scan to determine overall efficacy, safety, and effectiveness of endoluminal devices.[2,25] Our current FDA protocol requirements include postoperative spiral CT scans, 3-, 6-, and 12-month duplex imaging, and a spiral CT scan at 1 year. Unexpected findings such as leaks or displacements are investigated further with angiography.[13]

The more serious risks of vascular surgery can be obviated by the judicious use of endovascular techniques.[42] Angiography, although the gold-standard method of imaging, and available since the 1920s,[41] can be replaced in many areas by less invasive and more accurate methods in the evaluation of patients with various vascular lesions. IVUS can take seconds to perform and be of particular use in real-time evaluation of the results. STI

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