Maintaining Stent Graft Limb Patency

Daniel G. Clair, MD, discusses the risk factors leading to limb failure and device elements that can help diminish this complication.



The literature has shown that there are several risk factors that may lead to stent graft limb occlusions. What are the primary anatomical and procedural risk factors for limb complications?

The anatomic risk factors affecting limb thrombosis include angulation, tortuosity, and smaller-diameter iliac vessels, along with extensive calcification. These factors can affect not only limb thrombosis, but also delivery of the device to the treatment site. Additionally, the flow channel through the aneurysm can affect limb patency, as aneurysms with either extensive thrombus or some anatomic constriction within the flow channel can lead to compression of one or both limbs, which can reduce limb patency. In general, narrow or significantly angulated anatomy is a predisposition to limb thrombosis. An additional anatomic factor affecting limb patency is outflow anatomy. In most situations, the larger the vascular outflow bed, the better the patency of the limb, so restricted vascular outflow can negatively affect limb patency and increase the risk of thrombosis.

The primary procedural risk factors for limb thrombosis include some things that can be as simple as inadequate anticoagulation during the case. If thrombus is present, either in the graft itself or the outflow vessels, there is an increased risk of graft thrombosis. Significant angulation in the limb or graft itself can limit flow through the graft and lead to thrombosis, so these issues need to be addressed at the time of the procedure. Graft limbs ending in angulated anatomy need to be adequately assessed to ensure the limb is not ending directly into a severe angle that is restricting flow. These distal endpoint issues can often be addressed by either extending the graft limb or transitioning the graft limb into the native iliac anatomy with self-expanding stents. Injury or damage to the iliac vessels during insertion can lead to impaired patency rates, especially if the injury is flow-limiting and unrecognized. For example, this can happen when there is a dissection where the introducer sheath is located and the area of the sheath insertion is not imaged during completion imaging. Damage to the vessels at the point of insertion is particularly problematic, because this type of injury often cannot be assessed during completion

imaging and may not occur until closure of the access point. Another critical factor is that the more distal in the anatomic bed the limb is placed, the higher the likelihood of occlusion. Therefore, graft limbs ending in the external iliac artery have lower patency rates than those placed in the common iliac artery.

How does stent graft design and material affect potential limb complications?

There is evidence that unsupported limbs have lower patency rates than fully supported limbs. Currently, there are really no devices in use with unsupported limbs. There is also at least some evidence that polytetrafluoroethylene (PTFE) is potentially associated with lower limb thrombosis rates, perhaps due to less inflammation, when compared with alternative fabrics (i.e., PET, also known as polyester/Dacron). In addition, there are some grafts with better flexibility, which will sit better in some anatomies and allow better accommodation of the graft and less limb kinking. It also is clear that larger limb diameters have better patency rates, although this needs to be taken in the context of assessing the vessel into which the device is being placed. Severely oversizing a limb into a small external iliac artery does not improve patency. In general, larger limbs provide better patency rates, but there is perhaps some evidence that shorter limbs improve patency as well.

Of all the previously discussed risk factors, which are responsible for the majority of limb occlusions?

Of these aforementioned factors, graft limb kinking and distal vessel disease appear to be the most common issues associated with graft limb thrombosis. More than the other causes, these two issues affect flow and can lead to thrombosis both early and late postprocedure.

Which endovascular aneurysm repair (EVAR) techniques may help reduce limb complications?

EVAR techniques to prevent this problem include utilizing a graft that will be the best fit for the patient and ensuring that outflow disease is treated adequately before completing the procedure. In choosing a graft, consider the iliac artery anatomy and ensure that the limbs are

flexible enough to accommodate the iliac flexibility. In patients with severe iliac disease, smaller device delivery systems should be chosen, and wire and device insertion should be carefully performed to avoid dissection. Completion imaging should include the iliac arteries below the point of graft insertion and may require removal of the device delivery sheath, as well as imaging of the vessels after the sheath has been removed to ensure that there is no vessel damage and there is good flow through the iliac artery below the stent graft limb. When the iliac artery is severely diseased or dissection of the vessel is noted, stenting should be part of the initial procedure.

Limb kinking can be addressed by additional supportive stenting within the limb as well. This is best assessed upon completion imaging with rigid wires removed, so the graft conforms to the position it will be in after all devices and equipment are removed. In patients with evidence of limb kinking, the treatment depends on the location and severity of the problem. In patients in whom the severe angulation is at the aortic bifurcation, the use of a "crossed-limb" technique can minimize the angulation at the proximal iliac arteries. For angulation at the distal end of the limb, accommodative, selfexpanding stent placement will allow better positioning and flow through the limb distally. In patients with a narrow channel aortic lumen, dilating both limbs simultaneously with large-diameter balloons is often all that is required to adequately dilate the limbs and ensure adequate caliber of the limb flow channels. If this alone is inadequate, then stenting (performed simultaneously in the two limbs) can overcome the compressive force. It is important to remember that these stents need to be positioned at the same point in the limbs, as the placement of stents can lead to contralateral limb occlusion if the stent crushes the other limb lumen. Here again, completion imaging with adequate assessment, sometimes in two planes, is critical to ensuring the best outcomes.

If a limb thrombosis or occlusion does occur after an EVAR procedure, when does it typically present?

Generally, limb thrombosis tends to occur early on, with the vast majority presenting in the first year, and most of these occurring in the first 3 months. More than 50% of limb thrombosis occurs within 3 months of graft placement. These early failures are much more likely related to technical errors during the procedure, and in most instances, these should be considered avoidable.

What are the surgical and endovascular treatment options for limb occlusion?

The open surgical options can be directed to the occluded limb itself, performing open surgical limb thrombectomy from the groin or even from the iliac

artery with or without iliofemoral bypass. Surgical thrombectomy is often performed with an over-the-wire balloon thrombectomy catheter to ensure access through the limb and even imaging of the limb after surgical thrombectomy is completed. Alternatively, revascularization can be achieved with extra-anatomic bypass grafting, either through femorofemoral bypass grafting or axillofemoral bypass grafting. An operator might choose one of these extra-anatomic techniques when thrombectomy or interventional therapies have failed to open the affected limb. One might also choose this option if the patient has had severe ischemia for an extended period, as this is often the fastest method of achieving blood flow restoration to the limb.

Endovascular options include mechanical thrombectomy, pharmacomechanical thrombus treatment, and standard thrombolytic therapy. Physician experience along with the acuity of the process may drive this decision. The more acute or significant the symptoms, the more a combined pharmacologic agent combined with a mechanical device will be helpful. In many instances, some combination of lytic therapy and mechanical device will be required, and it is imperative that an underlying cause be identified and treated. In most instances, this will involve angioplasty and stenting to resolve a kink, stenosis, or dissection.

Has the introduction of lower-profile systems increased or decreased the risk factors for limb complications? If so, why?

Although I know of no specific study relating the profile of an endograft delivery system to graft limb thrombosis, it is clearly evident that lower-profile devices now allow treatment of aortic aneurysm without the use of conduits that would have been required before. Additionally, a low-profile delivery system appears to induce fewer problems with vessel injury, including iliac artery perforation and dissection. Finally, the low-profile delivery system allows imaging of the outflow tract beyond the delivery sheath (as the delivery system is often much smaller than the iliac vessel) to assess runoff vessels, even with the sheath in place.

Recent EVAR investigational device exemption studies and peer-reviewed literature have reported limb occlusion rates ranging from 1% to 7%. How do the published data influence your choice of EVAR device?

Data on graft limb thrombosis rates show variations for differing devices, with lower rates for PTFE grafts when compared to others. In general, a number of features, including proximal neck anatomy (size, calcification, angulation, and length), iliac vessel tortuosity, and diameter, as well as other factors, drives decisions regarding endograft use specific to an individual patient's anatomic

issues. Although limb thrombosis rates do not directly drive graft choice, iliac artery angulation, calcification, and size do factor into the decision-making process. In general, the choice of endograft is based on an attempt to use the most appropriate device for each individual's specific anatomic needs. In those with limited anatomic issues, the choice is often dictated by physician familiarity and comfort, which should be an additional part of the decision-making process.

How would you describe the ideal stent graft and delivery system in regard to the aim of reducing the risk of limb complications?

The ideal stent graft and delivery system to limit stent graft limb thrombosis would be a low-profile delivery system with well-supported, flexible limbs that could adequately accommodate to tortuous anatomy and allow full expansion with placement in narrow aortic or

iliac anatomy. The system would have adequate radial force to overcome stenosis and the ability to accommodate a variety of anatomies. The delivery system itself would not only be low-profile, but would also be flexible and hydrophilic to limit or diminish insertion forces and dissection. Ideally, this system would serve as a working sheath, so that multiple device insertions would not be required in situations where additional interventions are required, and orientation would be easily achieved in situ, so that significant manipulations would not be required to ensure precise positioning and orientation of the graft.

Daniel G. Clair, MD, is Chair of the Department of Vascular Surgery, the Cleveland Clinic Foundation in Cleveland, Ohio. He has disclosed that he provides educational speaker services to TriVascular. Dr. Clair may be reached at (216) 444-3857; claird@ccf.org.