Pararenal Aortic Aneurysms

Off-the-Shelf Devices Should Be Used

Standardized technology allows interventionists to treat patients on an individual basis with the most appropriate device indicated for aneurysm presentations.

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The treatment of aortic aneurysms with proximal anatomic challenges has been approached in several different ways, each of which carries with it advantages and disadvantages. Open repair remains the primary therapy for healthy candidates in most practices, but in patients with increased risk, modifications of endovascular devices and techniques can offer alternative options. Depending on practice preferences, these techniques are also being used in some patients who are considered good candidates for open surgery. However, modified devices often require extensive time and expense to create and use, and in some instances, these devices have not been adequately tested. Device expense can be significant with every option for treating pararenal aneurysms. Physicians can expect scrutiny regarding the relationship between procedure costs and outcomes, and, more broadly, between these costs and their impact on availability given limited resources. Clearly, there will be pressure via current reimbursement policies to favor lower-cost, evidence-based interventions.

Pararenal aortic aneurysm repair due to the lack of an infrarenal neck demands a unique approach either via customized stent grafts (eg, fenestrated endografts) or off-the-shelf adjuncts (eg, chimney technique). In light of all considerations, we submit that pararenal aortic aneurysms are ideally repaired with commercially available, off-the-shelf devices when possible.

For these devices, there has been preclinical testing of the system, and we have data regarding the performance of the procedure (likely revealing a decrease in the periprocedural risk of repair compared with open repair), and long-term data regarding the outcomes of these repairs as opposed to those performed with physician-modified options and untested combinations of other devices. Additionally, our ability to have these items readily available increases the applicability of this technology to patients with proximal aneurysm morphologic challenges.

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CHIMNEY TECHNIQUE OVERVIEW

The umbrella term *off-the-shelf* comprises a number of techniques that exist along a spectrum of applicability and sophistication. Chimney (or "snorkel") techniques were initially developed as a rescue option[1] and since have been used intentionally in anticipation of visceral artery coverage. The essential technique is conceptually straightforward: First, the target vessel (ie, the renal artery) is accessed via a brachial approach. After wire

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exchange, a long sheath is positioned within the renal artery. The aortic endograft is then placed, followed by deployment of the renal artery stent, which is typically balloon-expandable and covered. The final step is simultaneous molding balloon angioplasty of the target vessel and aortic endograft. The desired result is adequate endograft seal with antegrade target vessel flow from a more proximal point.

Although near-term results of small groups treated with the chimney technique have been favorable, no long-term analysis of a sizeable cohort exists. Resch et al reported 25 cases of planned chimney grafts for short-necked abdominal aortic aneurysms with either unfavorable neck angulation or iliac access.[1] The majority of patients (17/25) required acute repair secondary to rupture or a symptomatic aneurysm. All patients received bilateral renal stents except for four who received unilateral renal stenting with contralateral coverage; two patients additionally underwent superior mesenteric artery (SMA) chimney grafts. Three patients with ruptured abdominal aortic aneurysms died within 24 hours: two had complete exclusion of the aneurysm, and the third had a type Ia endoleak that was not addressed secondary to the patient's poor medical condition. Using computed tomography at a mean follow-up of 10 months, three type I endoleaks were discovered: one abated spontaneously, one was successfully treated and the patient later died of nonaneurysm-related causes, and one had persistent endoleak in the context of a shrinking sac. A single renal chimney graft occlusion was detected, and attempts at recanalization were unsuccessful.

Simplicity and possibly lower cost are key advantages of chimney graft techniques.[2] The critical shortcoming of the option is the lack of long-term data required for clarification of appropriate use. For instance, placement of chimney grafts leads to the creation of paraendograft gutters. It is unclear at this point, however, what length of gutter is required for gutter thrombosis. Likewise, stability of the chimney graft alongside the aneurysm endograft and the relationship between chimney graft number and endoleak risk are unknown.

It is also worthwhile to mention the sandwich technique, which is a variant of the chimney technique that has been used for thoracoabdominal aneurysms. Like the chimney technique, it too lacks data to allow robust conclusions. In brief, a proximal thoracic endograft is deployed, followed by placement of chimney grafts as previously described. Then, a distal aortic endograft is deployed, overlapping the proximal endograft, which effectively sandwiches and stabilizes the chimney grafts.

THE VENTANA STENT GRAFT

The Ventana Fenestrated System (Endologix, Inc., Irvine, CA) is an investigational device in the United States based on the AFX stent graft (Endologix, Inc.) and is intended as an off-the-shelf device for juxtarenal and pararenal aortic aneurysms. A key feature of the Ventana device is the ability to manipulate or steer the renal fenestrations radially (90–210°) and longitudinally (up to 30 mm) in situ, enabling treatment of a wide range of visceral anatomies. The device contains two 3-mm renal fenestrations available in aligned or offset renal artery configurations. The fenestrations are precannulated with 6.5-F sheaths, thus simplifying renal artery access. The Ventana stent graft remains fully constrained while the renal arteries are cannulated, facilitating maneuverability. A 4-cm proximal scallop is provided for preservation of the celiac and superior mesenteric arteries. This integrated system includes the Xpand balloon-expandable renal stent grafts (Endologix, Inc.) that are delivered through the Ventana delivery system 6.5-F sheaths and across the fenestrations to assist in maintaining the patency of the renal arteries. The most proximal segments of the Xpand devices are designed for flaring in the aorta with a 10-mm balloon.

Deployment consists first of anatomically fixing the AFX bifurcated device such that its proximal edge lands 1 to 3 cm below the lowest renal artery. The 22-F Ventana delivery system is then introduced, and the outer sheath is slightly retracted to expose the preloaded renal artery sheaths. A 0.035-inch guidewire and selective angiographic catheter are advanced through each 6.5-F sheath. The wires and catheters provide a framework to advance sheaths into the renal arteries, and once these are properly positioned and advanced within the renal arteries, the delivery system is advanced until the scallop is fluoroscopically verified to be positioned at the base of the SMA. The device is then fully deployed, and the renal stents are expanded. Early and midterm results from the Ventana Pilot Study will be presented at the 40th annual symposium of the Society for Clinical Vascular Surgery.

THE PIVOT GRAFT

The Pivot graft (Cook Medical, Bloomington, IN) is based on Cook Medical's Zenith graft and the Zenith Fenestrated device. Modification of the fenestrations to a 15-mm domed outer diameter creates "pivot fenestrations," which allow access to arteries within the 15-mm outer diameter of the domed fenestration. The stents placed through these reinforced nitinol fenestrations can pivot and direct flow from the inner portion into the cannulated vessel. The graft includes a fixed 8-mm fenestration positioned at 12 o'clock for the superior mesenteric artery. Based on anatomic evaluation of branch vessel

positions in 100 patients (unpublished data), more than 70% of target vessels can be accommodated by using one of two graft designs. Flexibility within the graft fabric will likely allow access to a superior mesenteric artery at the noon position and thus possibly allow accommodation of more patients than initially predicted.

The device is packaged with preloaded wires through the renal fenestrations, over which 6-F sheaths can be advanced to allow tracking directly though the fenestrations. This concept of preloaded fenestrations has previously been described and reported.[3] With a modification of a previous design, a single 0.018-inch wire passes through the side port of the delivery handle, through the main body of the graft, out of one renal fenestration, across the graft, into the other renal fenestration, back through the main body of the graft, and finally, out through the second side port on the delivery handle.

A reverse-tapered tip is fitted on the proximal aspect of the delivery cannula, forming a tapered profile to allow easy retrieval of the top cap when the proximal uncovered fixation stent is deployed. This bare-top stent is identical to the top stent of the standard Zenith graft. The deployment of the graft is similar to the deployment of the standard custom fenestrated stent graft, with the major difference being unilateral renal artery catheterization and the preloaded wire. The device is now enrolling patients in a trial to attempt to receive CE Mark. Enrollment of half of the required 30 patients has been completed.

MODIFIED STANDARD INFRARENAL GRAFTS

This technique involves predeployment of an infrarenal graft with creation of fenestrations to accommodate vessels. The device is then repackaged within the deployment system and delivered. Fenestrations are cannulated after the graft is deployed, and the branches are then cannulated. The device may be partially constrained as part of the modification of the system to allow room around the outside of the device to access the branches. Results of this technique have been reported, and short-term results appear similar to those reported for custom-made devices. The largest experience reported involves the Zenith device as the basis for this technique.[4] There have been no evaluations of the compatibility of components used to perform this technique, and for this reason, midterm and longer-term results are mandatory before more widespread application of this technique.

CONCLUSION

Pararenal aortic aneurysms can be treated with a variety of endovascular methods. The chimney/snorkel/sandwich technique is conceptually simple but lacks data on short-term procedural safety, device compatibility, and long-term efficacy. In addition, the costs of these procedures can be exorbitant, as multiple devices are often needed for branch stability. Surgeon-modified stent graft repair based on high-quality computed tomographic angiography is an alternative but is subject to the imprecision inherent in the process of manually tailoring each graft. Additionally, these techniques lack system compatibility testing and any information more than short-term efficacy data. Here again, cost can be a significant consideration, as multiple devices from various manufacturers are combined to create a solution.

Custom fabricated fenestrated stent grafts provide a sophisticated, viable, and effective treatment for pararenal aneurysms. The principal disadvantages are cost, complexity of deployment, and the 4- to 6-week interval (at least) from initial imaging to final stent graft availability. The Ventana and the Pivot branch systems attempt to combine the virtues of customized fenestrated grafts while avoiding the cost and prolonged fabrication time.

Final conclusions are pending trial completion. There are no definitive data at present to allow for adequate comparison of the various endovascular pararenal aneurysm repair approaches. Nevertheless, the economic and logistical advantages of off-the-shelf repair are compelling and intuitively apparent. Off-the-shelf options offer physicians the potential to expand the application of endovascular technology, especially in urgent and emergent settings, but also in elective settings, to ensure that patients are treated with the most appropriate indicated device rather than relying on technologies pushed beyond their testing limits, which inherently places them at a higher risk for failure. ■

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