Endovascular Management of Refractory Type I Endoleaks

Tools and techniques to allow tailored endoleak resolution and ultimately decrease aneurysm rupture rates.

BY JOHN MORIARTY, MD, AND MAHMOOD K. RAZAVI, MD, FSIR, FSVM

Endovascular repair of thoracic (TEVAR) or abdominal aortic aneurysms (EVAR) has proven to be a safe, popular, and effective treatment option for managing aortic aneurysms. However, a major ongoing challenge to the near-universal use of endografts has been to create an endograft that ensures the same reliable aneurysm seal afforded by open surgical resection and suturing of a prosthetic graft directly to the aortic wall.

Prevention of leakage at these seal sites, also known as type I endoleaks (EL1), is made difficult if there are anatomic features such as short necks, severe neck angulation or tortuosity, large neck diameter, or thrombus at the landing zone site. The presence of a single one of these, or more frequently a combination of these factors, leaves the aneurysm sac open to arterial flow and pressure (and hence still at an increased risk of rupture), with 74% of post-EVAR ruptures attributed to EL1.1 Management of EL1 is therefore of critical concern and should be immediately addressed once diagnosed.

CLASSIFICATION OF TYPE I ENDOLEAKS

Endoleaks have been reported to occur in 10% to 30% of patients at any time during postprocedure follow-up2,3; however, the majority of endoleaks are of the type II (EL2) variety and are of uncertain clinical significance in the absence of aneurysm sac enlargement. EL1 are less frequent, with an overall incidence thought to be between 5% and 15%, depending on the series, generation of device, and operator experience; intraoperative EL1 are reported at a rate of 3% to 7%.4,5 Furthermore, EL1 are a common cause of conversion to open repair post-EVAR and were responsible for 39% of conversions in one series.6

EL1 may occur in one of three ways: (1) EL1A originate from the proximal seal zone; (2) EL1B originate from the distal seal zone and are more frequently associated with TEVAR of thoracoabdominal aneurysms with short distal landing zones to the celiac artery; and (3) the rare EL1C, which occurs at the site of an iliac occluder if an aorto-uni-iliac stent graft has been deployed. EL1A are the most frequent form and are associated with high-risk features such as proximal neck angulation of > 45° to 60° and conical or very short aortic necks. In EL1B, aortic neck diameter and distal attachment site diameter do not seem to play as big of a role.7,8

Classically, management of EL1 is attempted at the time of implantation after identifying the endoleak on intraprocedural angiography. According to the clinical practice guidelines of the Society for Vascular Surgery and the European Society for Vascular Surgery, all EL1
should be treated to prevent rupture. The use of balloon angioplasty or stent graft extension with an aortic extender may be considered; however, with short necks and concern over coverage of renal (EVAR) or supra-aortic (TEVAR) vessels, options may be limited, and additional endovascular techniques may be required once the EL1 has been confirmed.

**BARE-METAL STENTING TO INCREASE WALL APPPOSITION**

EL1 can develop when there is suboptimal wall apposition of the stent graft at the seal zone. Most are resolved by simple balloon angioplasty of the device. In case of EL1 refractory to balloon dilation, a common mechanism for resolution is to increase the centrifugal force of the graft on the aortic wall by deploying a balloon-expandable stent to overlap the seal zone. The high radial force of devices, such as Palmaz stents (Cordis Corporation, Bridgewater, NJ), allows molding of the stent graft to the intimal surface of the aorta while reducing the risk of side-branch compromise that is associated with the use of aortic extenders.

Several groups have published good technical success and follow-up with this technique, with analysis of a large cohort of 162 Palmaz stents in 1,470 EVAR procedures demonstrating that Palmaz stent deployment itself is not an independent predictor of either increased 30-day mortality or of poorer long-term survival, although it is associated with an increased incidence of EL1 and reintervention. Although malapposition of large-caliber, hand-mounted stents (eg, Palmaz stents) is not uncommon, several techniques have evolved to improve landing zone accuracy, such as pre-expanding the proximal and distal ends of the mounting balloon prior to placement of a short stent within the sheath or partial deployment of a long stent while constraining the distal aspect within a long delivery sheath.

Figure 1. Contrast-enhanced CT angiography (CTA) demonstrating contrast outside of the endograft, representing an endoleak (A). Aortography demonstrating a type IA endoleak (arrows) with pooling of contrast outside the graft (B). A reverse-curve catheter was hooked over the top of the endograft (C). A microcatheter was advanced through the reverse-curve catheter into the aneurysm sac in the confirmed position within the endoleak (D). The endoleak was embolized using Onyx liquid embolic, with complete filling of the space (E). Filling of a residual entering artery (arrows) was seen, indicated a concomitant type II endoleak, now treated. Completion aortography demonstrated no residual endoleak or filling of the aneurysm sac (F).
Figure 2. CTA demonstrating a large endoleak around an endograft, as seen on both axial (A) and coronal (B) reconstructions. Aortography confirmed the presence of the endoleak (arrows) and demonstrated flow from the distal aspect of the endograft (type EL1B) (C). The EL1B was confirmed on retrograde injection with contrast seen filling the sac from below (D). Wire access into the site of endoleak was achieved after wedging the catheter adjacent to the graft (arrows; E). Transcatheter embolization was performed with a combination of coils (arrows; F) and Onyx (G), which were brought down to the inferior aspect of the aneurysm sac. Completion retrograde angiography was unremarkable, with resolution of the EL1B (H). Follow-up CTA confirmed occlusion of the endoleak and interval sac size reduction (I).
**Endovascular Embolization of the Endoleak Tract**

Balloon-expandable bare-metal stents and proximal stent graft extensions may sometimes fail or not be suitable to manage all EL1, particularly when angulation of the neck is severe or if the neck is of sufficiently large diameter that placement of a Palmaz stent is not feasible. In these situations, embolization of either the sac or the feeding endoleak tract may be beneficial in decreasing arterial pressurization of the sac.

Endovascular access into the sac with EL1A is usually accomplished with a combination of a reverse-curve catheter, such as a Cobra or Sidewinder (Cordis Corporation) hooked over the proximal edge of the stent graft, with a microcatheter then advanced through the tract distally into the sac (Figure 1). For EL1B access, typically an angled catheter, such as a KMP catheter (Cook Medical, Bloomington, IN), is wedged between the wall of the aorta or iliac vessel and the stent graft, with subsequent retrograde passage of a microcatheter into the sac (Figure 2). An alternative and simpler approach is device extension into the external iliac artery after embolization of the ipsilateral hypogastric artery. The status of the contralateral hypogastric artery and preservation of pelvic flow should be considered in the latter approach.

Once access into the sac has been achieved, a decision as to which embolic agent to use must be made. Coil embolization is the most commonly used method, most likely due to widespread facility with the technology, and the use of coils in this setting has been described with excellent technical success for nearly 20 years. However, liquid embolics have the potential added bonus of either more distal embolization than is capable with coils or an adhesive effect, as is seen with glue. Hence, interventionists have used liquid embolics (eg, Onyx, Covidien, Mansfield, MA), fibrin glue or n-butyl-2-cyanoacrylate in both EVAR and TEVAR, with good technical success and a low complication rate.

**Direct Sac Puncture with Embolization of the Tract**

Direct sac puncture allows the operator to bypass the need for endovascular selective cannulation of the endoleak source and has a well-published and disseminated role in the management of EL2 in either the thoracic or abdominal aorta. An interesting feature of these data is that sacography following direct puncture for a presumed EL2 frequently identifies EL1, occurring in three of 21 cases in a large recent series. Two of these three patients were successfully treated with a thrombin injection, and the third required cuff extension. The efficacy of this technique was born out by Mehta et al, who reported a 70% success rate with translumbar coil embolization of EL1. We prefer the use of liquid embolic agents over thrombin for two main reasons. First, the potential for recanalization of the tract is less likely due to the permanent nature of liquid embolics. Second, the better visualization of liquid agents reduces the risk for nontarget embolization.

**Endovascular Fixation of the Endograft to the Aortic Wall**

Adequate fixation of the endograft to the aortic wall is typically determined by the radial strength of a suitably oversized stent; however, when this is insufficient, the stent graft can be mechanically “stapled” or “anchored” to the landing zone. There are several devices currently on or coming to the market, led by the Heli-FX EndoAnchor system (Aptus Endosystems, Inc., Sunnyvale, CA), which received US Food and Drug Administration clearance in November 2011.

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Figure 3. The initial angiogram demonstrated a short, tapered neck from a thoracoabdominal aneurysm to the celiac artery (A). Aptus EndoAnchors were placed in a circular pattern around the inferior aspect of the stent graft to fixate it to the landing zone (B). Completion angiogram shows good fixation with no leakage or endoleak (C).

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The device consists of two complementary devices: a 16-F outer-diameter deflectable guide sheath (Hi-Fi FX Guide) and an electromechanical delivery device (Hi-Fi FX Applicer) that implants the EndoAnchor (Figure 3). The EndoAnchor itself is a helical “screw-like” implant with an atraumatic conical tip and is made of a metal alloy. It is 4.5 mm in length, 3 mm in diameter, and made of a round wire that measures 0.5 mm in diameter. A minimum of four EndoAnchors are recommended for aortic necks up to 29 mm in diameter, and at least six EndoAnchors are needed for larger necks. It features a tapered needlepoint that allows penetration through diffusely calcified vascular tissue but prevents overpenetration through the adventitia of the aortic wall while still being able to withstand a force of 20 N (in a silastic model).26

The use of EndoAnchors has been studied with an array of different endografts, including Zenith (Cook Medical), Endurant (Medtronic, Inc., Santa Rosa, CA), Excluder (Gore & Associates, Flagstaff, AZ), Talent (Medtronic, Inc.), and AneuRx (Medtronic, Inc.).27,28 The Heli-FX Thoracic EndoAnchor system is indicated for use in patients with type I endoleak or migration, as well as managing “bird-beaking” of stent grafts in the arch. So far, there have been no reported cases of type III endoleak formation due to graft tears at the anchor site.

CONCLUSION

Endovascular techniques for managing EL1 have evolved so that the aortic interventionist has an armamentarium of tools, which can be tailored to each individual case. These include the addition of balloon-mounted stents or EndoAnchors to improve fixation or embolization of either the sac or endoleak tract to decrease inflow. These techniques, as well as evolving mechanisms of extending the landing zone to help prevent EL1 in the first place (eg, fenestrated grafts or snorkels/chimneys) should help decrease rupture rates and improve outcomes.

John Moriarty, MD, is a vascular and interventional radiologist at UCLA Medical Center and Assistant Clinical Professor at the David Geffen School of Medicine at UCLA in Los Angeles, California. He has disclosed that he has no financial interests related to this article. Dr. Moriarty may be reached at jmoriarty@mednet.ucla.edu.

Mahmood K. Razavi, MD, FSIR, FSVRM, is Director, Department of Clinical Trials, St. Joseph Heart & Vascular Center in Orange, California. During the last 12 months, Dr. Razavi has been an advisor to Abbott Vascular, Cordis, Boston Scientific, Bard, TriVascular, and Veniti, and received grant funding from Gore & Associates.