Can All rAAAs Be Treated Endovascularly?

The current data on open versus endovascular repair and the adjunct techniques you need to know to ensure an optimal result with EVAR.

BY THOMAS LARZON, MD, PhD

bservational studies and registries comparing endovascular aneurysm repair (EVAR) with open repair (OR) for ruptured abdominal aortic aneurysms (rAAAs) have suggested a benefit for EVAR¹⁻³ but have been brought into question by the results of randomized controlled trials (RCTs). Both the Amsterdam Acute Aneurysm trial⁴ and the IMPROVE trial⁵ could not find any significant difference in operative or short-term mortality rates between the two treatment types. The outcomes of patients with rAAAs also varies in different countries, as does the number of patients who are considered to be eligible for EVAR.^{2,3} The ratio of patients who are offered aneurysm repair also varies between countries, and hospital-level factors affect outcomes, as patients who are treated in a teaching institution tend to have better outcomes than those treated elsewhere.6

Dedicated centers, however, have shown that it is possible to completely replace OR with EVAR by using adjunctive techniques while keeping a very low exclusion rate of patients who are not offered any treatment.^{7,8}

This article discusses the appropriate management of rAAAs and describes different adjunct techniques when endovascular treatment is chosen.

AORTIC CROSS-CLAMPING

Specific protocols for instant insertion of an aortic occlusion catheter are crucial for success in emergency EVAR and should be well known by the entire team. However, the use of aortic balloon occlusion (ABO) is not free from complications, and even pronounced hypotension can be accepted as long as the patient

remains conscious or does not deteriorate with convincing signs of ongoing extravasation and expansion of the intra-abdominal hematoma. Balloon inflation should only be carried out when truly necessary; approximately 19% to 27% of patients with rAAAs require aortic cross-clamping with ABO. 1.4.8

The transfemoral approach is the recommended access route for the aortic occlusion catheter. Initially, an axillary approach was suggested because of downward displacement in the aneurysm sac during femoral insertion. This problem is solved by the sheath itself, which supports the balloon. The side that is less favorable for insertion of the stent graft serves as the access route for the occlusion balloon. The thoracic aorta is cannulated via the ruptured aneurysm with a soft guidewire and then exchanged to a stiff guidewire, and an appropriately sized sheath is inserted into the aorta. The sheath should be long enough to support an inflated balloon. Angiography is performed via the sheath, and deployment of the stent graft's main body and ipsilateral leg can be done with the occlusion balloon inflated. Via the ipsilateral side, a new balloon is inflated inside the main body, and the primary suprarenal balloon may now be deflated and withdrawn via the sheath, thereby maintaining circulatory control and also restoring circulation to the visceral branches. Staged declamping upon completion of the procedure is good practice.

HOSTILE PROXIMAL MORPHOLOGY

Severe angulation; a short, conical, or wide aortic neck; or thrombosis at the landing zone are all factors that might prevent standard EVAR of an AAA. By using fenes-

trated or branched stent grafts, sealing can be accomplished at the suprarenal, supramesenteric, or supraceliac levels. Most of these systems are custom-made devices, which limits their use in practice to elective cases. In an acute setting, different adjunct branch-preserving techniques are necessary.

Chimney Technique

Chimneys or parallel grafts are stents or stent grafts that are used to create a landing zone where the main graft would ordinarily cover branch vessels. The basic principle for the chimney technique is deploying a stent graft parallel to the aortic stent graft into a branch vessel from a brachial or axillary access. ^{10,11} Before insertion, it is important to evaluate the entire aorta and the different access routes with CT angiography. A tortuous thoracic aorta will normally make it more challenging to catheterize branch vessels, and thrombus formation or stenosis of the branch vessels will increase the difficulty. In such situations, axillary access can be used, which allows a shorter introducer sheath, and as a consequence, a greater variety of catheters will be available to cannulate the branch vessels.

The stent graft that is used for a chimney can either be balloon-expandable or self-expandable. There are pros and cons to both types. The balloon-expandable graft kinks more easily but makes it easier to reinsert the introducer over the balloon into the stent. Furthermore, if balloon dilatation of the aortic stent graft is necessary, the balloons are already inserted and can be inflated in the chimney grafts to prevent collapse. The size of the chimney is usually selected without special oversizing. Approximately 10 to 15 mm of the chimney should be inside the branch vessel, and the top of the chimney should be at least 5 mm above the main graft. The chimney should preferably land in a straight portion of the branch vessel, and if necessary, a flexible nitinol stent extension can be used to avoid kink formation. To get as good a sealing zone as possible, it is important to come close to the superior mesenteric artery with the main body.

The chimney technique can also be used in unstable rAAAs where ABO is necessary. It is possible to catheterize the renal arteries and insert chimneys via introducers placed parallel to the balloon. However, occlusion time is crucial for the visceral circulation, and it seems reasonable to consider sacrificing one renal artery in cases of time-consuming catheterization.

Lift Technique

One of the limitations with the chimney technique is the necessity of proximal access, which restricts the possibility to get access because of anatomical variations of the renal arteries. Lachat et al¹² has described the lift

technique as an alternative. Through a femoral access, followed by an 8-F sheath, the target renal vessel is cannulated, and a chimney graft is advanced 1 to 2 cm into the renal artery and deployed such that its proximal end faces downward. The distal end is fixed in place with an inflated angioplasty balloon. A stiff guidewire is inserted coaxially through the 8-F sheath, the guidewire is removed from the renal artery, and the 8-F sheath is carefully pushed over the stiff guidewire, lifting the chimney graft upward. With the chimney reoriented cranially, the aortic stent graft is immediately deployed.

Physician-Modified Grafts

Physician-modified endovascular grafts are feasible in emergencies for operators familiar with all technical aspects and potential risks of the technique. Modifications of stent grafts are performed under sterile conditions starting immediately before the patient is taken to the endovascular suite. The time required for device manufacture ranges from 30 to 80 minutes, depending on the number of fenestrations. The entire device, or portion of the device, is unsheathed. The system is resheathed, depending on what system has been used.¹³ Use of physician-modified endovascular grafts has been described as a safe and effective alternative for treating patients with juxtarenal aneurysms who have no other alternatives for repair, as well as in ruptured aneurysms.¹⁴

HOSTILE DISTAL MORPHOLOGY

The indication for a distal extension to the external iliac artery (EIA) in acute EVAR is usually an inadequate landing zone in the common iliac artery (CIA). Preoperative or intraoperative embolization can be used in elective surgery and is also applicable to treat rAAAs. In select cases, an iliac branch device can be used to preserve internal iliac artery (IIA) flow.

Embolization Techniques

Coils are safe and reliable embolic agents for endoleak treatment and the most common technique to embolize the IIA. A disadvantage with coil embolization is the risk for downstream displacement, which might lead to ischemic complications.

Vascular plugs are embolic devices that can sometimes be excellent alternatives to coils. Plugs are easy to precisely deploy and are commonly used to embolize medium- to large-sized high-flow vessels with little risk of migration or recanalization. Unlike coil embolization, it is possible to occlude the vessel right at the ostium and is therefore useful in IIA embolization.

In tortuous, narrow, or highly angled anatomy, coils and plugs can be technically demanding, and

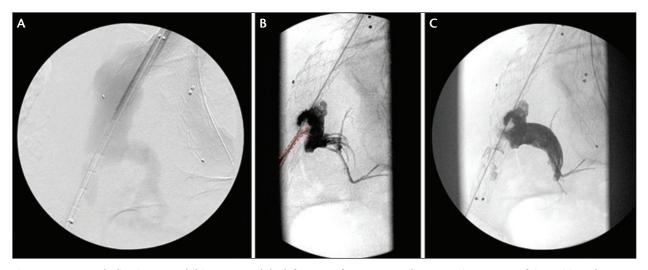


Figure 1. Onyx embolization to prohibit type II endoleak from IIA after EVAR. An iliac extension stent graft is positioned to cover the IIA artery but is not deployed (A). A macrocatheter (dashed line) is placed with its tip in CIA and after deployment of the extension; stent graft polymer strands into the IIA has been created by multiple interval injections of Onyx (B). Final result of the procedure (C).

an alternative is to use a liquid embolic agent. Onyx (Medtronic) consists of ethylene vinyl alcohol copolymer dissolved in dimethyl sulfoxide and tantalum powder to make it highly radiopaque. As Onyx is injected in the bloodstream, it forms a cast with a harder outer layer and a liquid core. This allows a long continuous injection, and Onyx is easily used to embolize a vessel far from the catheter tip.¹⁵

Technically, the aortic stent graft is deployed, distally predetermined to reach the CIA, but not down to the EIA. An iliac extension stent graft is positioned to cover the IIA artery but is not deployed. Through the same introducer or another femoral puncture, a dimethyl sulfoxide—compatible macrocatheter is inserted with the catheter tip placed free in the CIA and as close as possible to the origin of the IIA. It is not necessary to get direct access to the IIA. The iliac extension stent graft is then deployed.

Onyx embolization can then be performed with minimal risk for downstream embolization. During continuous slow injection and fluoroscopic monitoring, a plug of the polymer is formed at the catheter tip. Continuous injection will form a cast of the IIA and the CIA aneurysm sac. Repositioning of the catheter can be performed to facilitate Onyx deployment toward the planned target area (Figure 1).¹⁶ In a ruptured aortoiliac aneurysm, the Onyx injection takes place when all of the stent grafts have been deployed.

TYPE I ENDOLEAKS

A type I endoleak seen on completion angiography cannot be accepted, and all attempts must be taken to

resolve it, even if it is a minor one. Distal type I endoleaks can be easily treated by distal extension to the EIA in combination with the Onyx embolization technique previously described, if necessary.

Proximal type I endoleaks are often much more challenging to treat with interventional techniques. Aortic cuffs and bare stents can be used to optimize the proximal sealing zone. Suprarenal extension can be achieved using the chimney technique, and embolization can be used to seal the gutters, which is a problem sometimes

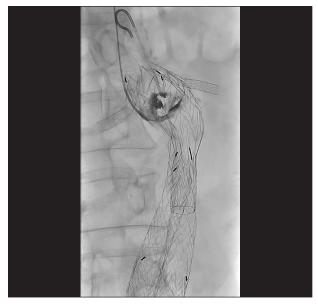


Figure 2. Type I endoleak after chimney treatment. Onyx embolization via proximal access through a gutter.

seen with the chimney technique (Figure 2). A quick way to achieve sealing at the proximal neck is to leave one or two catheters in the aneurysm sac, outside the deployed stent grafts. These catheters can be used for injection of Onyx to create a "collar" around the stent graft (Figure 3).

SINGLE-CENTER EXPERIENCES

Since May 2009, all patients with an rAAA have been treated with EVAR at Örebro University Hospital in Sweden. Preoperative CT angiography is always performed and is the basis for choosing surgical strategy, graft sizing, and system. A restriction of intravenous fluids is routine, and the target systolic blood pressure is 70 to 90 mm Hg. Local anesthesia is the preferred method, but initial local anesthesia combined with later general anesthesia or total general anesthesia has also been used in patients with severe pain to prevent them from moving, improve imaging, and allow precise stent graft deployment. ABO over a stiff guidewire and with a supporting sheath has been used only when cardiovascular collapse has occurred perioperatively.^{7,17}

From May 2009 until December 2013, 70 patients arrived at Örebro University Hospital with an rAAA. Six of 70 patients (9%) were considered unfit for any intervention (including open repair) and were not offered any intervention. Total mortality in this cohort was 23 of 70 patients (33%). The remaining 64 patients were all treated with EVAR, and 30-day mortality in this group was 17 of 64 patients (27%). Thirty-four (53%) of the surgically treated patients were in hemodynamic shock, with a systolic blood pressure below 80 during transport or in the hospital before surgery was initiated. Mortality was not statistically significantly higher among patients who had been in shock compared with patients who were never in shock (P = .264; X^2 test). Forty patients (63%) underwent only local anesthesia during the entire procedure. Some patients initially underwent local anesthesia but were converted to general anesthesia during the procedure. Those who only underwent general anesthesia had a significantly higher mortality rate compared to the other patients (P = .009; X^2 test). Seventeen (27%) received ABO treatment during the procedure, and mortality in this group was significantly increased (P = .004; X^2 test).

Eighteen patients (28%) either had at least one branch vessel (IIA or a renal artery) intentionally covered or embolized or one or two chimneys to preserve circulation to the renal arteries. Mortality was not significantly different between patients with or without branch vessel occlusion (P = .992) or with or without chimneys (P = .693) using the X² test.

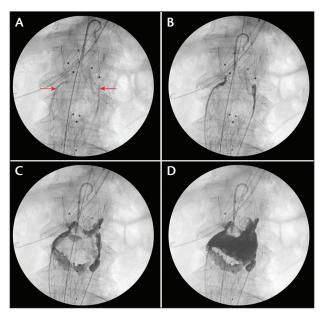


Figure 3. Embolization technique to seal a type I endoleak after EVAR. Two catheters are placed in the top of the aneurysm sac (outside the stent grafts) in cases where type I endoleak is expected. The arrows mark the tip of the catheters (A). Injection of Onyx through both catheters (B). During continuous injection, a collar is created around the proximal neck (C). Final result (D).

DISCUSSION

Considerable controversy exists regarding the superiority of EVAR compared to OR in treating rAAAs. A recent meta-analysis claims that regardless of the number of observational studies and registries showing improved mortality with an EVAR, they all suffer from the same inherent biases that tend to favor EVAR. Treatment algorithms and surgeons' decisions are considered to direct patients to OR in hemodynamically unstable situations and to EVAR if patients are hemodynamically stable.

RCTs, on the other hand, have observed no significant difference in short-term (30-day) mortality between EVAR and OR but have been criticized for being flawed, mainly based on the randomization process.¹⁹ In four European RCTs, a high exclusion rate (51%–78%) was reported. In the IMPROVE trial, almost half the patients in the EVAR limb were deemed unsuitable for EVAR and were then referred for OR,⁵ and a single morphological parameter, aneurysm neck length, appeared to have a significant influence on operative mortality following surgery for rAAAs, independent of known confounders. As the aneurysm neck shortened, conventional EVAR was either impossible or carried a very high mortality rate.²⁰

However, it has been shown that all patients with rAAAs can be treated with EVAR with a low exclusion rate

COVER STORY

provided there is a protocol for an "EVAR-only approach" and sufficient knowledge about how to use adjunctive techniques.⁷ Our own experiences encompass a continuous period of 56 months with 100% EVAR procedures and an exclusion rate of only 9%.⁸ The main arguments for selection bias can therefore hardly be considered relevant. This must be compared with recently published data from the Hospital Episode Statistics for England and the Nationwide Inpatient Sample for the United States for patients admitted to hospitals with rAAAs from 2005 to 2010. The rejection rate was between 20% to 57% in the United States and 42% to 55% in England.⁶

How can we optimize treatment in the future? Improved survival has been seen after introducing specific protocols.^{21,22} Internal logistics must be thoroughly planned, and the logistics of working with external hospitals are equally important. Team training using high-fidelity simulation may be one answer to allow clinicians to learn, practice, rehearse, maintain, and improve team-based knowledge.²³ An appropriate inventory of suitable stent grafts and accessories must be stocked and available for the procedure and unexpected eventualities. A toolbox of different access techniques is crucial for an endovascular approach.

As the endovascular strategy becomes more and more dominant in elective treatment, it will undoubtedly be more and more difficult to provide high-quality 24/7 OR service. In the future, we can predict that emergency treatment will probably favor endovascular methods, boosted by new products entering the market (eg, onthe-shelf systems with the ability to preserve circulation to branches). New technologies and concepts for endovascular aortic sealing may also have a significant impact.

In conclusion, the data show that OR of rAAAs can be replaced with EVAR when there is appropriate management of existing adjunct techniques.

Thomas Larzon, MD, PhD, is Head of Vascular Surgery, Department of Cardiothoracic and Vascular Surgery, Faculty of Medicine and Health, Örebro University in Örebro Sweden. He has disclosed that he has a proctoring, training, speaking, and consulting agreement with Covidien AG, Switzerland. Dr. Larzon may be reached at thomas.larzon@regionorebrolan.se.

- Veith FJ, Lachat M, Mayer D, et al. Collected world and single center experience with endovascular treatment of ruptured abdominal aortic aneurysms. Ann Surg. 2009;250:818-824.
- Gibbons C; on behalf of the European Society for Vascular Surgery. Second Vascular Surgery Database Report 2008. European Society for Vascular Surgery website. http://www.esvs.org/sites/default/files/file/Vascunet/Vascunet9620report96202008.pdf. Accessed February 7, 2015.
- 3. Park BD, Azefor N, Huang CC, et al. Trends in treatment of ruptured abdominal aortic aneurysm: impact of endovascular repair and implications for future care. J Am Coll Surg. 2013;216:745–754; discussion 754–755.
- Reimerink JJ, Hoornweg LL, Vahl AC, et al; Amsterdam Acute Aneurysm Trial Collaborators. Endovascular repair versus open repair of ruptured abdominal aortic aneurysms: a multicenter randomized controlled trial. Ann Surg. 2013;258:248-256.
- 5. IMPROVE trial Investigators, Powell JT, Sweeting MJ, et al. Endovascular or open repair strategy for ruptured

- abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial. BMJ. 2014;348:f7661.

 6. Karthikesalingam A. Holt P.I. Vidal-Diez A. et al. Mortality from runtured abdominal agrific aneurysms: clinical
- Karthikesalingam A, Holt PJ, Vidal-Diez A, et al. Mortality from ruptured abdominal aortic aneurysms: clinical lessons from a comparison of outcomes in England and the USA. Lancet. 2014;383:963-969.
- Mayer D, Aeschbacher S, Pfammatter T, et al. Complete replacement of open repair for ruptured abdominal aortic aneurysms by endovascular aneurysm repair: a two-center 14-year experience. Ann Surg. 2012;256:688-695; discussion 695-696.
- Larzon T, Skoog P. One hundred percent of ruptured aortic abdominal aneurysms can be treated endovascularly if adjunct techniques are used such as chimneys, periscopes and embolization. J Cardiovasc Surg (Torino). 2014;55:169-178.
 Malina M, Holst J. Balloon control for ruptured AAAs: when and when not to use? J Cardiovasc Surg (Torino). 2014;55:161-167
- 10. Larzon T, Eliasson K, Gruber G. Top-fenestrating technique in stent grafting of aortic diseases with mid-term follow-up. J Cardiovasc Surg (Torino). 2008;49:317–322.
- 11. Ohrlander T, Sonesson B, Ivancev K, et al. The chimney graft: a technique for preserving or rescuing aortic branch vessels in stent-graft sealing zones. J Endovasc Ther. 2008;15:427-432.
- 12. Lachat M, Bisdas T, Rancic Z, et al. Chimney endografting for pararenal aortic pathologies using transfermoral access and the lift technique. J Endovasc Ther. 2013;20:492–497.
- 13. Oderich GS, Ricotta JJ 2nd. Modified fenestrated stent grafts: device design, modifications, implantation, and current applications. Perspect Vasc Surg Endovasc Ther. 2009;21:157–167.
- 14. Starnes BW. Physician-modified endovascular grafts for the treatment of elective, symptomatic, or ruptured juxtarenal aortic aneurysms. J Vasc Surg. 2012;56:601-607.
- 15. Hörer T, Toivola A, Larzon T. Embolization with Onyx in iatrogenic bleeding of the gluteal region. Innovations (Phila). 2011;6:267–270.
- 16. Larzon T, Hörer T. Plugging and sealing technique by Onyx to prevent type II endoleak in ruptured abdominal aortic aneurysm. Vascular. 2013;21:87-91.
- 17. Larzon T, Lindgren R, Norgren L. Endovascular treatment of ruptured abdominal aortic aneurysms: a shift of the paradiom? J Endovasc Ther. 2005;12:548–555.
- Van Beek SC, Conijn AP, Koelemay MJ, et al. Editor's Choice—Endovascular aneurysm repair versus open repair for patients with a ruptured abdominal aortic aneurysm: a systematic review and meta-analysis of short-term survival. Eur J Vasc Endovasc Surg. 2014;47:593-602.
- 19. Mayer D, Rancic Z, Veith FJ, et al. Part two: against the motion. EVAR offers no survival benefit over open repair for the treatment of ruptured abdominal aortic aneurysms. Eur J Vasc Endovasc Surg. 2015;49:119–127.
- 20. IMPROVE Trial Investigators. The effect of aortic morphology on peri-operative mortality of ruptured abdominal aortic aneurysm [published online ahead of print January 27, 2015]. Eur Heart J.
- 21. Moore R, Nutley M, Cina CS, et al. Improved survival after introduction of an emergency endovascular therapy protocol for ruptured abdominal aortic aneurysms. J Vasc Surg. 2007;45:443–450.
- 22. Mehta M, Kreienberg PB, Roddy SP, et al. Ruptured abdominal aortic aneurysm: endovascular program development and results. Semin Vasc Surg. 2010;23:206-214.
- 23. Van Herzeele I, Sevdalis N, Lachat M, et al. Team training in ruptured EVAR. J Cardiovasc Surg (Torino). 2014;55:193–206.