

Sponsored by TriVascular, Inc.

New Options for EVAR in Women

Overcoming the anatomical variations of AAAs in women with a new ultra-low-profile endograft.

BY AMIT JAIN, MBBS, MS; JOHN A. KERN, MD; AND SAHER SABRI, MD

Endovascular aneurysm repair (EVAR) has been shown to improve early and midterm mortality rates when compared to open repair by multiple randomized trials and observational studies to date.¹⁻³ In general, treatment of abdominal aortic aneurysms (AAAs) in women has been associated with greater complications than in men. When compared to men, a higher percentage of women present with ruptured AAAs.⁴ They have poor outcomes with both open and endovascular repair in elective as well as emergent settings when compared to men.⁴⁻⁸

Significant anatomical variations of AAAs between men and women make women less likely to be eligible for meeting the instructions for use criteria for the majority of the traditional, larger-profile EVAR devices. Both the aorta and the iliac arteries tend to be smaller in women, as well as AAAs with shorter infrarenal aortic necks that more frequently involve juxtarenal and suprarenal aortic segments.⁹ A retrospective analysis of more than 1,000 CT scans of patients with infrarenal AAAs from a single center suggests that AAAs in women tend to have shorter and more angulated necks.⁶ This study also revealed that 47% of women had bilateral iliac artery diameters smaller than 6 mm compared to only 17% in men.

The Ovation Prime™ abdominal endograft (TriVascular, Inc., Santa Rosa, CA), a newer EVAR device, has an infrarenal AAA neck requirement of 7 mm, which expands the EVAR eligibility regardless of gender, and its low-profile delivery system (14-F outer diameter) provides an invaluable tool in extending EVAR possibilities for patients with smaller iliac arteries. Another major advantage of the Ovation Prime abdominal endograft lies in its effectiveness in treating AAAs in patients with small proximal aortic neck diameters. It is currently approved to treat a minimal aortic diameter of 16 mm.

CASE EXAMPLE

An 82-year-old woman with diabetes mellitus, obesity, obstructive sleep apnea, spinal stenosis, diverticulosis, and skin cancer was followed for her expanding infrarenal AAA,

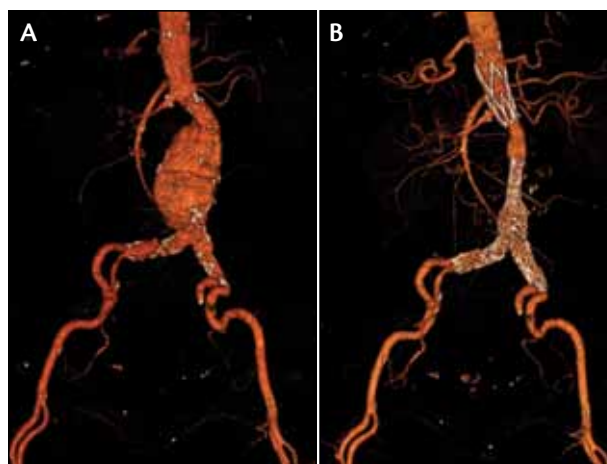


Figure 1. A preoperative CT scan showing a proximal aortic neck diameter of 15.6 mm, angulated neck, and tortuous iliac arteries (A). A 30-day postoperative CT scan with an excluded AAA and patent bilateral renal and internal iliac arteries (B).

which measured 5.0 X 4.4 cm on a recent CT scan. She was referred to our clinic for evaluation. Her CT scan revealed an infrarenal AAA with a small-diameter aortic neck (average, 15.5 mm) located 13 mm below the lowest renal artery (Figure 1A). The distal common iliac arteries were 11.1 mm on the right and 12.9 mm on the left. The minimum size of the access vessels was 7.5 mm on the right and 7.6 mm for the left external iliac artery. There was significant tortuosity noted in both the iliac arteries. The infrarenal neck angulation was moderate, at approximately 45°. The native aortic bifurcation was 17 mm in diameter.

Due to the small diameter of the aorta, the use of available US Food and Drug Administration–approved devices was limited. Most available devices are limited to 18- to 19-mm aortic neck diameters per the instructions for use. However, the Ovation device allows the treatment of aortic neck diameters as small as 16 mm.

We chose a 20-mm Ovation Prime device and the left side as the primary access site because it was slightly

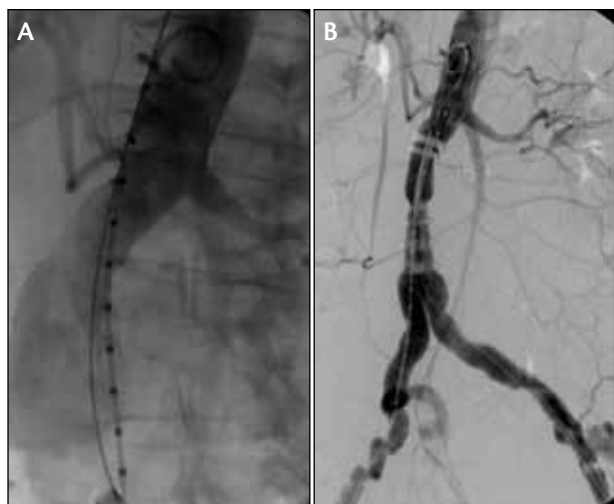


Figure 2. Predeployment angiogram (A). Postdeployment completion angiogram with preserved renal and pelvic perfusion and no endoleaks (B).

less tortuous than the right. Under ultrasound guidance, bilateral percutaneous accesses were achieved, and two Perclose ProGlide® sutures (Abbott Vascular, Santa Clara, CA) were placed on each side. The main body device was deployed with the radiopaque markers at the level of the lowest right renal artery (Figure 2A). Next, the radiopaque, low-viscosity, biocompatible polymer was introduced into the sealing rings and confirmed with fluoroscopy. The contralateral gate was cannulated, and a 14- X 120-mm iliac limb was deployed. The same size limb was deployed on the left side. Completion angiography confirmed excellent endograft placement, exclusion of the AAA, no endoleaks, and preserved bilateral pelvic flow via the internal iliac arteries (Figure 2B).

After discharge, the patient was followed up at 1 month, and the CT scan (Figure 1B) showed excellent graft placement, patent renal and bilateral internal iliac arteries, and a stable aneurysm sac size with no evidence of any endoleaks.

DISCUSSION

The new Ovation Prime abdominal endograft has expanded the eligibility criteria for AAAs to be treated endovascularly, with inclusion criteria of a proximal aortic neck length ≥ 7 mm, inner neck diameter between 16 and 30 mm, and distal iliac diameter between 8 and 20 mm.¹⁰ An important subset of the population to benefit from this device is likely to be women who have AAAs with smaller native aortic diameters, smaller access vessels, and shorter necks. These anatomical variations that differentiate AAAs in women from men are also responsible for the higher failure rates and complications rates of EVAR with traditional larger-profile devices.⁷

Although some studies have suggested that women derive less benefit from elective EVAR than men,⁸ others have shown that the survival benefit of EVAR was sustained for 6 years in women but disappeared in 2 years for men.⁹ Almost all of these older studies included EVAR performed with traditional larger-profile devices, which required aortic neck lengths ≥ 10 mm. Newer data on lower-profile delivery systems have shown equivalent outcomes between the genders despite anatomic differences in women.^{10,11}

Of these newer devices, the Ovation Prime abdominal stent graft system, with the lowest-profile delivery system and ability to treat smaller and shorter neck diameters, holds particular promise in women who have AAAs with challenging anatomical variations. This ultra-low-profile device also facilitates percutaneous access, quicker recovery, and a shorter hospital stay. ■

Amit Jain, MBBS, MS, is a fellow physician, Department of Vascular Surgery, University of Virginia Health System in Charlottesville, Virginia. He stated that he has no financial interests related to this article. Dr. Jain may be reached at amitmaks@gmail.com.

John A. Kern, MD, is Chief, Division of Cardiothoracic Surgery; Surgical Director, Heart Transplantation/Mechanical Circulatory Assist Devices; and Surgical Director, Heart & Vascular Center, University of Virginia, in Charlottesville, Virginia. He stated that he has no financial interests related to this article. Dr. Kern may be reached at (434) 982-4301; jak3r@virginia.edu.

Saher Sabri, MD, is Associate Professor of Radiology and Surgery; Vice Chair of Education, Department of Radiology; Radiology Residency Program Director, Division of Interventional Radiology, University of Virginia Health System in Charlottesville, Virginia. He stated that he has no financial interests related to this article. Dr. Sabri may be reached at (434) 924-9401; ss2bp@virginia.edu.

1. United Kingdom EVAR Trial Investigators, Greenhalgh RM, Brown LC, et al. Endovascular versus open repair of abdominal aortic aneurysm. *N Engl J Med.* 2010; 362:1863-1871.
2. Lederle FA, Freischlag JA, Kyriakides TC, et al; the OVER Veterans Affairs Cooperative Study Group. Long-term comparison of endovascular and open repair of abdominal aortic aneurysm. *N Engl J Med.* 2012;367:1988-1997.
3. Dangas G, O'Connor D, Firwana B, et al. Open versus endovascular stent graft repair of abdominal aortic aneurysms: a meta-analysis of randomized trials. *JACC Cardiovasc Interv.* 2012;5:1071-1080.
4. McPhee JT, Hill JS, Eslami MH. The impact of gender on presentation, therapy, and mortality of abdominal aortic aneurysm in the United States, 2001-2004. *J Vasc Surg.* 2007;45:891-899.
5. Lo RC, Bensen RP, Hamdan AD, et al; Vascular Study Group of New England. Gender differences in abdominal aortic aneurysm presentation, repair, and mortality in the Vascular Study Group of New England. *J Vasc Surg.* 2013;57:1261-1268.
6. Sweet MP, Fillingim MF, Morrison TM, et al. The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair. *J Vasc Surg.* 2011;54:931-937.
7. Abedi NN, Davenport DL, Xenos E, et al. Gender and 30-day outcome in patients undergoing endovascular aneurysm repair (EVAR): an analysis using the ACS NSQIP dataset. *J Vasc Surg.* 2009;50:486-491.
8. Mehta M, Byrne WJ, Robinson H, et al. Women derive less benefit from elective endovascular aneurysm repair than men. *J Vasc Surg.* 2012;55:906-913.
9. Egorova NN, Vouyouka AG, McKinsey JF, et al. Effect of gender on long-term survival after abdominal aortic aneurysm repair based on results from the Medicare national database. *J Vasc Surg.* 2011;54:1-12.
10. Mehta M, Valdes FE, Nolte T, et al; A Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the Ovation Abdominal Stent Graft System Investigators. One-year outcomes from an international study of the Ovation abdominal stent graft system for endovascular aneurysm repair. *J Vasc Surg.* In press.
11. Dubois L, Novick TV, Harris JR, et al. Outcomes after endovascular abdominal aortic aneurysm repair are equivalent between genders despite anatomic differences in women. *J Vasc Surg.* 2013;57:382-389.