

Real-World Experience

What we have learned thus far from the midterm results of the European OVATION® Post-Market Registry.

BY DIERK SCHEINERT, MD

Although endovascular aneurysm repair (EVAR) has now become the treatment of choice for patients with abdominal aortic aneurysms (AAAs), we continue to witness tremendous advances in EVAR technology with smaller-caliber and more flexible delivery systems, improved sealing technologies, and expanded size offerings, all in an effort to expand the eligible patient population and improve long-term treatment durability. Still, a considerable opportunity for EVAR innovation remains, as a substantial proportion of AAA patients remains ineligible for treatment with an endograft due to their anatomical characteristics.¹ Additionally, durable aneurysmal exclusion remains an elusive therapeutic goal, with higher reintervention rates with EVAR compared to open surgical repair.²

The Ovation and Ovation Prime® stent graft systems (TriVascular, Inc.) were specifically designed to overcome and address the main limitations of traditional EVAR stent grafts by providing low-profile access using a 14-F (outer diameter) delivery system, active suprarenal fixation, and a durable O-ring sealing mechanism that provides a custom, gasket-like fit even in short, tortuous, or irregular aortic necks without exerting chronic radial force on the aortic wall. The Ovation device has been commercially available in Europe since receiving CE Mark approval in August 2010 and in the United States since US Food and Drug Administration approval in October 2012, which was in part based on the impressive results from the Ovation Global Pivotal Trial.³ The Ovation Prime stent graft system has been commercially available in Europe since June 2012 and in the United States since December 2012. In the global pivotal trial, 161 patients were electively treated with the Ovation stent graft for AAA, including 65 patients who were not eligible for EVAR with other commercially available stent grafts. During 1-year follow-up, there were no technical failures, AAA ruptures, conversions to open surgery, migrations, or type I/III endoleaks. Freedom from AAA-related mortality was 99.4%, and AAA enlargement was identified in

only two patients (1.3%). The 2-year data from this study were recently presented and look equally impressive.

Human clinical trials are fundamental to the medical device development process. Clinical trials of endovascular devices are generally conducted at experienced centers in highly selected patients in an effort to minimize the impact of confounding factors on study outcomes. Although the internal validity of clinical trials increases when strict controls on patient selection, surgical technique, and user experience are implemented, external validity usually suffers. Put simply, the outcomes reported in clinical trials are oftentimes not generalizable to patients treated in routine clinical practice.

In order to demonstrate that clinical trial results with the Ovation system were representative of the outcomes in patients treated in a real-world setting, the OVATION registry was initiated. The OVATION Post-Market Registry is a postmarket study of the Ovation and Ovation Prime stent grafts conducted at 30 European centers, many with no prior experience with the device. This article summarizes our experience thus far using the Ovation stent grafts in the OVATION registry, outside the rigorous constraints of a traditional clinical trial.

THE OVATION REGISTRY: STUDY DESIGN AND MAIN OUTCOMES

Patients enrolled in this prospective, single-arm, post-market study were anatomically suitable for the Ovation stent graft based on the indication for use statements. All patients underwent CT angiography of the abdomen and pelvis to confirm anatomic suitability for the Ovation or Ovation Prime endografts. Follow-up imaging and procedures were performed in accordance with routine clinical practice at each site and will continue for 5 years.

Between May 2011 and December 2013, 501 consecutive patients were enrolled at 30 European centers. Most patients (86%) were men, and the mean age was 73 years. As a whole, these patients presented with very challenging anatomy: 42% had narrow (< 7 mm) access

vessels, 21% had short (< 15 mm) proximal necks, and moderate/severe neck calcium and thrombus were observed in approximately 50% of patients. Bilateral percutaneous access was performed in 39% of patients, and 63% of patients underwent general anesthesia. Patients were treated with the Ovation (n = 264) or Ovation Prime (n = 235) stent graft. Procedural blood loss was minimal (median, 100 mL), and technical success was 99.6%.

Follow-up in this study is ongoing, with more than 50% of patients with 1-year data available. Radiographic findings include 0.9% AAA enlargement, 0.4% type I endoleak, 0.4% type III endoleak, 0% migration, and 0% limb occlusion. Through 1 year, there has been one (0.2%) AAA rupture (contained) and one (0.2%) surgical conversion; 6.4% of patients have undergone secondary procedures. Only 0.3% AAA-related secondary procedures have been reported in the 2-year follow-up window (366–730 days). Interestingly, neither female sex nor complex aortic anatomy increased the risk for device-related complications.

THE LEIPZIG OVATION REGISTRY EXPERIENCE

At our center, Park Hospital in Leipzig, we enrolled 41 consecutive patients in the OVATION registry between December 2011 and December 2013. The mean patient age was 72.3 years, with most (88%) patients being men. Overall, the registry patients presented with very challenging anatomy: 40% had narrow (< 7 mm) access vessels, which was similar to the population of the OVATION registry. In contrast, the patients at our

center had much more hostile neck anatomy than in the registry, with more than 50% of the patients presenting with a short (< 15 mm) proximal neck. Totally percutaneous access was achieved in 97.6% of patients, and 97.6% of patients did not require general anesthesia. Patients were treated with the Ovation (n = 13) or Ovation Prime (n = 28) stent graft. Procedural blood loss was minimal (median, 100 mL), and technical success was 100%.

Follow-up at our center in this study is ongoing, with more than 56% of patients with 1-year data available. Radiographic findings at 1 year include no AAA enlargement, no type I/III endoleak, no migration, and no limb occlusion. Through 1 year, there have been no AAA ruptures and no surgical conversions, and only two patients have undergone secondary procedures. One of the procedures was for treatment of a persistent type Ia endoleak at 1-month follow-up, which was resolved with coils, and one for treatment of a type II endoleak, which was treated with coils and thrombin injection.

In order to further highlight the clinical utility of the Ovation systems, we have selected a case from the registry that was treated at our center.

CASE STUDY: OVATION REGISTRY

A 78-year-old man with renal failure and a tumor was followed for his expanding infrarenal AAA, which measured 42 mm (Figure 1A). He was referred to our clinic for evaluation. His CT scan revealed an infrarenal AAA with a small-diameter aortic neck (average, 21 mm) at

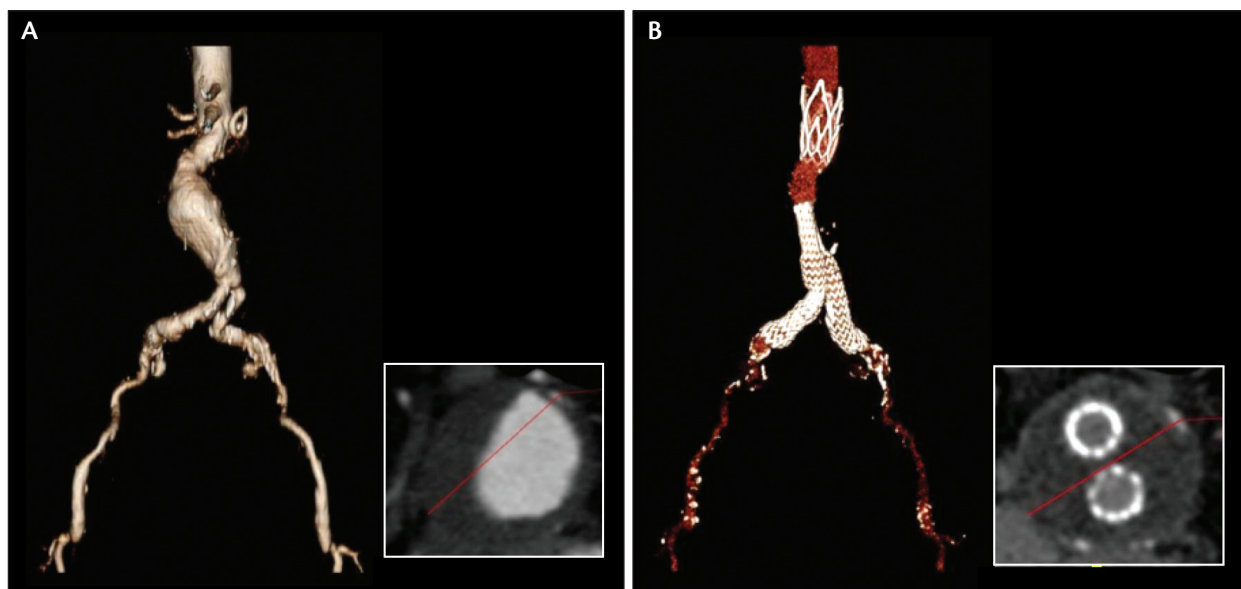


Figure 1. Preoperative imaging of a AAA measuring 42 mm (A). Follow-up imaging showing successful aneurysm exclusion and AAA shrinkage to 37.6 mm (B).

the location of the sealing ring, 13 mm below the lowest renal artery. The distal common iliac arteries were 15 mm on the right and 13.3 mm on the left. There was significant tortuosity noted in both of the iliac arteries. The juxtarenal neck angulation was moderate, at approximately 43°. The native aortic bifurcation was narrow, with a minimum diameter of 18 mm.

This was our second consecutive patient treated in the OVATION registry. We chose a 26-mm Ovation stent graft and the right side as the primary access site because it was slightly less tortuous than the left. The patient was placed under local anesthesia, and under ultrasound guidance, bilateral percutaneous access was achieved. Two Perclose ProGlide or Prostar sutures (Abbott Vascular) were placed on each side. The main body was deployed, followed by the introduction of the radiopaque, low-viscosity, biocompatible polymer into the sealing rings. Next, the contralateral limb and ipsilateral limb were deployed. Completion angiography confirmed excellent endograft placement, exclusion of the AAA, and no endoleaks.

After discharge, the patient was followed up at 1 month, 6 months, 1 year, and 2 years. The most recent CT scan showed excellent graft placement, patent renal and bilateral internal iliac arteries, and a shrinking aneurysm sac (now down to 37.6 mm), with no evidence of any endoleaks (Figure 1B).

DISCUSSION

The midterm results from the OVATION registry demonstrated that EVAR using the Ovation and Ovation Prime stent grafts effectively treat patients with complex aortic anatomies in a real-world setting. Longer-term data from this registry will be required to confirm the durability of these midterm outcomes. Based on our personal experience with the Ovation systems, it has become a routine part of our treatment protocol for AAA due to its ability to treat a broad range of aortic anatomies with similarly impressive results. ■

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