Long-term outcomes of the Ovation Stent Graft System investigational device exemption trial for endovascular abdominal aortic aneurysm repair

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ABSTRACT

Objective: The objective of this study was to report the 5-year outcomes of the Food and Drug Administration investigational device exemption clinical trial of endovascular aneurysm repair (EVAR) with the Ovation stent graft (Endologix, Irvine, Calif) for elective treatment of abdominal aortic aneurysm (AAA).

Methods: The study comprised 161 patients who underwent EVAR as part of the prospective, international, multicenter pivotal Ovation stent graft trial. The main inclusion criteria were AAA diameter ≥5 cm, proximal neck length ≥7 mm, neck angulation ≤60 degrees, and bilateral iliac fixation length ≥10 mm. The primary end point was a composite outcome of primary clinical success at 5 years. Primary clinical success was defined in accordance with the Society for Vascular Surgery guidelines as successful aneurysm exclusion without aneurysm-related death, type I or type III endoleak, graft infection or thrombosis, aneurysm expansion, aneurysm rupture, graft migration, or conversion to open repair. Secondary end points included freedom from reintervention, all-cause mortality, and aneurysm-related mortality.

Results: Patients were predominantly male (87.6%) and elderly with a mean age of 73 ± 7.7 years; 66 patients (41%) had challenging anatomy and would be considered outside the instructions for use with other stent grafts, 26 (16.2%) had a proximal neck length <10 mm, and 53 (33%) had a minimum access vessel diameter <6 mm. Technical success was 100%. Of 126 surviving patients, 84 (66.7%) completed 5-year follow-up. The 5-year primary clinical success rate was 78%, aneurysm-related mortality was 1% (one patient), and all-cause mortality was 25%. The AAA-related death resulted from AAA post-EVAR rupture at 49 months in a patient who refused treatment for a type IB endoleak. Freedom from type I or type III endoleak was 95.1%. Freedom from secondary interventions was 80.2%. Most of the reinterventions were performed for type II endoleak (24 [63.1%]) or for limb thrombosis or stenosis (7 [18.4%]). There was no graft migration. None of the patients required open conversion.

Conclusions: Five-year results from the Ovation pivotal and continued access investigational device exemption trials demonstrate excellent long-term durability of this endograft despite that 41% of patients had anatomy unfit for other stent grafts. There were no migrations or conversions to open repair and 99% freedom from aneurysm-related mortality. These results suggest a less invasive on-label endovascular option for patients with challenging anatomy who may otherwise require hybrid or open repair. (J Vasc Surg 2020;72:1667-73.)

Keywords: EVAR; Ovation; Abdominal aortic aneurysm; Outcomes; Endoleak

Since the first endovascular aneurysm repair (EVAR) by Parodi et al[1] in 1991, EVAR has become the standard treatment for most patients with abdominal aortic aneurysm (AAA). The application of this minimally invasive technique in patients with suitable anatomy reduces the risk of early mortality and morbidity relative to open repair.[2-7] However, approximately 50% of patients with AAA requiring treatment are not eligible for on-label EVAR because of challenging anatomy,[8-11] most commonly short neck length, small access vessel diameter, and excessive neck angulation.[12,13] Whereas off-label EVAR is often attempted, nonadherence to

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Author conflict of interest: none.

Presented as an oral presentation at the Thirty-fourth Annual Meeting of the Western Vascular Society, Maui, Hawaii, September 28-October 1, 2019.

Additional material for this article may be found online at www.jvascsurg.org.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

Published by Elsevier Inc. on behalf of the Society for Vascular Surgery.

https://doi.org/10.1016/j.jvs.2020.01.066

anatomic guidelines specified in the manufacturer's instructions for use (IFU) has been associated with increased risk of aneurysm-related complications.[14] Furthermore, several randomized clinical trials have reported superior durability with open repair compared with EVAR.[15-17] A meta-analysis of all randomized clinical trials comparing EVAR with open repair confirmed the loss of the early survival benefit with EVAR over time.[18]

Safely expanding treatment eligibility and improving repair durability are the most important challenges to be solved in elective EVAR. With the rapid evolution of stent graft technology, dissemination of stent graft-specific long-term data are mandatory to assist patients and providers with making evidence-based treatment decisions. The Ovation stent graft (Endologix, Irvine, Calif) has been commercially available in the United States since 2012. A unique feature of this device is its ability to accommodate a wider range of aortoiliac features, to navigate through complex iliac and femoral access, and to provide a seal in complex proximal infrarenal aortic neck morphology. Among commercially available EVAR grafts in the United States, 5-year results of regulatory trials have been reported with Endurant (Medtronic, Minneapolis, Minn), Zenith (Cook Medical, Bloomington, Ind), and Excluder (W. L. Gore & Associates, Newark, Del).[19-21] Here, we report the 5-year results from a Food and Drug Administration investigational device exemption (IDE) clinical trial of EVAR with the Ovation stent graft for elective treatment of AAA.

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective, international, multicenter pivotal clinical trial
- **Key Findings:** Of 161 patients who underwent endovascular aneurysm repair with the Ovation stent graft, 41% had aortoiliac anatomy unfit for any other endograft. Freedom from aneurysm-related mortality was 99% and freedom from type I or type III endoleak was 95%. There were no migrations or conversions to open repair.
- **Take Home Message:** Endovascular aneurysm repair with the Ovation stent graft had favorable long-term durability despite that 41% of patients had anatomy unfit for other stent grafts.

METHODS

Ovation IDE trial. This was a prospective, consecutively enrolling, nonrandomized, multicenter clinical trial of the safety and efficacy of the Ovation Abdominal Stent Graft System in the treatment of patients with AAA. This international trial enrolled 161 patients at 36 sites in the United States, Germany, and Chile between November 2009 and May 2011. The main inclusion criteria were AAA diameter ≥5 cm, proximal parallel neck length ≥7 mm, inner wall diameter of no less than 16 mm and no more than 30.5 mm at 13 mm below the inferior renal artery, neck angulation ≤60 degrees, and bilateral iliac fixation length ≥10 mm. A detailed description of the study design and 1-year outcomes have been previously published.[22] The study protocol and informed consent were approved by an Institutional Review Board or ethics committees, and all study participants gave written informed consent before study participation.

Device description. The Ovation stent graft consists of a trimodular design with the aortic body delivered through a flexible hydrophilic coated 14F outer diameter catheter. The aortic body is composed of a low-permeability polytetrafluoroethylene (PTFE) graft and a suprarenal nitinol stent with integral anchors to achieve active fixation to the aortic wall. The aortic body contains a network of inflatable channels and sealing rings that are filled during deployment with a low-viscosity, radiopaque, biostable cross-linked polymer that cures in situ to create a conformable seal to the aortic neck without self-expanding characteristics. The Ovation iliac limbs are composed of highly flexible spiral nitinol stents encapsulated in low-permeability PTFE that are packaged in a low-profile 13F or 14F outer diameter delivery system. A detailed description of the device is included in the Ovation stent graft IFU.[23]

Follow-up. All patients enrolled in the study were scheduled to undergo follow-up examinations at 1 month, 6 months, and 12 months postoperatively and then annually for a total of 5 years from the index procedure. At each follow-up visit, patients underwent a physical examination, laboratory testing, contrast-enhanced spiral abdominal or pelvic computed tomography with the fine cuts at 2 mm, and four-view abdominal radiography. All measurements were performed using a workstation with dedicated reconstruction software and center lumen line reconstruction by an independent core lab.

A Clinical Events Committee adjudicated adverse events through 1 year, an independent imaging core laboratory analyzed imaging through 5 years, and a Data and Safety Monitoring Board provided study oversight.

Outcomes. The original primary safety end point for the trial was defined as the incidence of major adverse events at 30 days. This included all-cause mortality, myocardial infarction, stroke, renal failure, respiratory failure, paraplegia, bowel ischemia, and procedural blood loss ≥1000 mL.

The original primary effectiveness end point was treatment success at 12 months, which was defined as successful graft implantation with freedom from type I and type III endoleak, stent graft migration, sac enlargement >5 mm, aneurysm rupture, and conversion to open repair.

The 1-year outcomes reporting the safety and efficacy of the Ovation abdominal stent graft have been previously published.[22] The aim of this study was to report the 5-year outcomes after EVAR for infrarenal AAA using the Ovation stent graft. The primary end point was a composite outcome of primary clinical success at 5 years. Primary clinical success was defined in accordance with Society for Vascular Surgery reporting standards as successful aneurysm exclusion without aneurysm-related death, type I or type III endoleak, graft infection or thrombosis, aneurysm expansion, aneurysm rupture, graft migration, or conversion to open repair.[24,25]

Graft migration was defined as distal movement >10 mm or movement ≤10 mm resulting in secondary intervention as reported by Society for Vascular Surgery guidelines. Secondary end points included freedom from reintervention, all-cause mortality, and aneurysm-related mortality.

Statistical analysis. Descriptive statistics were performed using univariable analyses including mean and standard deviation for continuous variables and frequency and percentage for categorical variables.

Event-free survival rates were estimated using Kaplan-Meier methods. Statistical analysis was performed using Stata/SE 13 software (StataCorp LP, College Station, Tex). A *P* value of ≤ .05 was considered significant.

RESULTS

Study cohort

A total of 161 patients who met eligibility criteria underwent EVAR with the Ovation stent graft. Enrollment included 111 patients from 28 sites in the United States, 30 patients from 7 sites in Germany, and 20 patients from 1 site in Chile. All enrolled patients underwent successful implantation of the Ovation Stent Graft System. The mean age of the patients was 73 ± 7.7 years, 87.6% were male, and 92.6% were of white race. Most of the patients (n = 107 [66.4%]) were considered to be at high operative risk and were assigned to American Society of Anesthesiologists class 3 or class 4. The main comorbidities of the patients are described in Table I.

Baseline aneurysm characteristics

Mean aneurysm sac diameter was 54 ± 9 mm, and mean proximal neck length was 22.9 ± 12 mm. There were 66 patients (41%) who had a challenging anatomy and would be considered outside the IFU with other stent grafts; 26 patients (16.2%) had a proximal neck length <10 mm, and 53 (33%) had a minimum access vessel diameter <6 mm. A complete summary of anatomic characteristics is provided in Table II.

Five-year outcomes

At 5 years, clinical site-reported follow-up was available for 93 (73.8%) and imaging follow-up for 84 (66.7%) of 126 surviving patients.

Table I. Patient demographics and baseline medical history

Baseline characteristics	Study cohort (N = 161)
Age, years	73 ± 7.7
Male sex	141 (87.6)
White	149 (92.6)
BMI, kg/m^2	28.5 ± 6
ASA class	
1	9 (5.6)
2	45 (28)
3	96 (59.6)
4	11 (6.8)
Smoking	113 (70.2)
COPD	44 (27.3)
Hypertension	136 (84.5)
Hyperlipidemia	113 (70.2)
Diabetes	34 (21.1)
Cardiac disease	72 (44.7)
Kidney disease	22 (13.7)
PAOD	38 (23.6)
Cerebrovascular disease	21 (13)
Family history of AAA	10 (6.2)

AAA, Abdominal aortic aneurysm; *ASA*, American Society of Anesthesiologists; *BMI*, body mass index; *COPD*, chronic obstructive pulmonary disease; *PAOD*, peripheral artery obstructive disease.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation.

Death, rupture, and conversion to open repair. Thirty-five patients (21.7%) died during the 5 years of follow-up, 4 in the first year, 10 in the second year, 5 in the third year, and 8 each in years 4 and 5. Table III lists the adjudicated causes of death in all patients. The 5-year freedom from all-cause mortality was 75%, and freedom from aneurysm-related mortality was 99% (Fig 1). There was only one aneurysm-related death in a patient with type IB endoleak who refused treatment and died on postimplantation month 49 from an aneurysm rupture. No open conversions were performed during the 5-year follow-up.

Endoleak, secondary intervention, and migration. The 5-year primary clinical success rate was 78%. During follow-up, four type IA endoleaks (2.5%), one type IB endoleak (0.6%), and one type III endoleak (0.6%) were reported, yielding 95.1% freedom from type I or type III endoleak at 5 years (Fig 2). Of the four patients who developed type IA endoleak, only one patient had a neck length <10 mm.

Thirty-eight AAA-related reinterventions were required in 27 patients (16.8%), mostly performed for type II endoleak with aneurysm sac growth of >5 mm (n = 17 [10.5%]) or for limb thrombosis or stenosis (n = 7 [4.3%]). Of the seven patients who required a reintervention for limb thrombosis or stenosis, two had a minimum access diameter <6 mm.

Table II. Baseline aneurysm characteristics

Aneurysm characteristics	Study cohort (N = 161)
AAA diameter, cm	5.4 ± 0.9
Proximal neck diameter, mm	
At the level of the renal arteries	22.5 ± 2.7
7 mm infrarenal	22.1 ± 2.9
13 mm infrarenal	22.7 ± 3.1
Proximal neck length, mm	22.9 ± 12
Proximal neck length <10 mm	26 (16.2)
Proximal neck length <15 mm	49 (30.4)
Right CIA diameter, mm	13.9 ± 3
Left CIA diameter, mm	13.7 ± 3.3
Right minimum iliac access diameter, mm	7 ± 1.6
Left minimum iliac access diameter, mm	7 ± 1.6
Minimum access diameter <6 mm	53 (33)
Anatomy outside IFU with other stent graft	66 (41)
Infrarenal neck angulation, degrees	19.1 ± 13.5

AAA, Abdominal aortic aneurysm; *CIA*, common iliac artery; *IFU*, instructions for use.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation.

Table III. Causes of death

Cause of death	Patients (N = 161), No. (%)
All	35 (21.7)
AAA related	1 (0.6)
Cardiac	3 (1.8)
Pulmonary	8 (5)
Carcinoma	8 (5)
Infection	5 (3.1)
Other/unknown	10 (6.2)

AAA, Abdominal aortic aneurysm.

The indications for reintervention are summarized in Table IV. All secondary interventions are listed in the Supplementary Table (online only).

Freedom from secondary interventions at 5 years was 80% (Fig 2), and all procedures were determined to be successful at the time of completion. Throughout the 5 years, there was no graft migration.

Sac size changes. At 5 years, the maximum AAA diameter decreased by >5 mm in 44 of 84 patients (52.4%), remained stable in 27 of 84 (32.1%), and increased >5 mm in 13 of 84 patients (15.5%).

Mean AAA diameter among all patients decreased by 6 ± 13 mm (Fig 3).

All patients with sac enlargement at 5 years were noted to have had type II endoleak at some point during follow-up.

DISCUSSION

With continued advancements in EVAR technologies, considerable opportunity for innovation remains to further improve access to EVAR and to ensure durable aneurysmal exclusion in the long-term. This report provides 5-year data on the regulatory IDE study of the Ovation endograft. A previously published report confirmed excellent 1-year results of this novel EVAR graft using nitinol, PTFE, and polymer technology.[22] Numerous retrospective studies have since shown good midterm outcomes with the Ovation stent graft in a real-world setting among patients with both acceptable and challenging anatomy.[26-28]

Relative to other commercially available stent grafts, there are two main attributes of the Ovation device that allow expanded treatment indications. First is the low-profile 14F outer diameter (12F inner diameter) delivery system that allows access in narrow iliac arteries, which is the smallest profile of any currently commercially available stent grafts. The utility of the Ovation design can be appreciated because 33% of our patients had a minimum access vessel diameter <6 mm. Second is the polymer-based sealing mechanism that allows treatment in proximal necks with complex, irregular anatomy. These results are noteworthy because nearly 41% of the patients enrolled in the Ovation pivotal study had difficult anatomy such that they would be considered outside IFU with other stent grafts.[12] In a series of 106 EVAR patients evaluated relative to the IFU of various stent graft manufacturers, 72% of patients were anatomically eligible for Ovation but only 59% with Endurant, 55% with Excluder, 36% with Zenith, and 35% with Aorfix (Lombard, Oxfordshire, United Kingdom).[29] Similarly, Patelis et al[30] reported a 78.9% suitability rate for Ovation compared with 57.9% for Excluder and 52.6% for Zenith.

Obtaining an adequate and durable seal between the stent graft and the aortic wall remains a challenge, particularly among patients with short and irregular aortic necks. The sealing rings at the proximal neck of the Ovation stent graft provide uniform circumferential wall stress at its interface to the sealing zone with no outward force exerted on the aortic wall over a short distance, creating a watertight seal unique to this endograft.[31-33] In this study, there were no graft migrations throughout the 5 years of follow-up compared with 8.6% reported with traditional self-expanding stent grafts that exert radial forces at a constant pressure on the aortic wall.[34] There was 2.5% type IA endoleak in this cohort at 5 years despite the fact that 16% of patients had proximal neck shorter than 10 mm. The low rates of type I or type III endoleak and secondary interventions compare favorably with other endograft regulatory

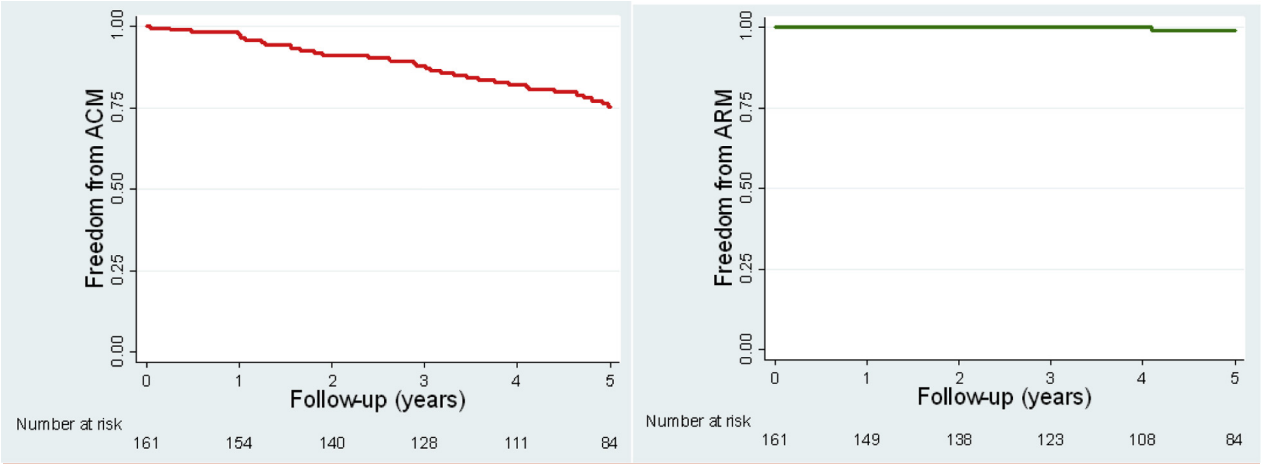

Fig 1. Freedom from all-cause mortality (*ACM*) and aneurysm-related mortality (*ARM*).

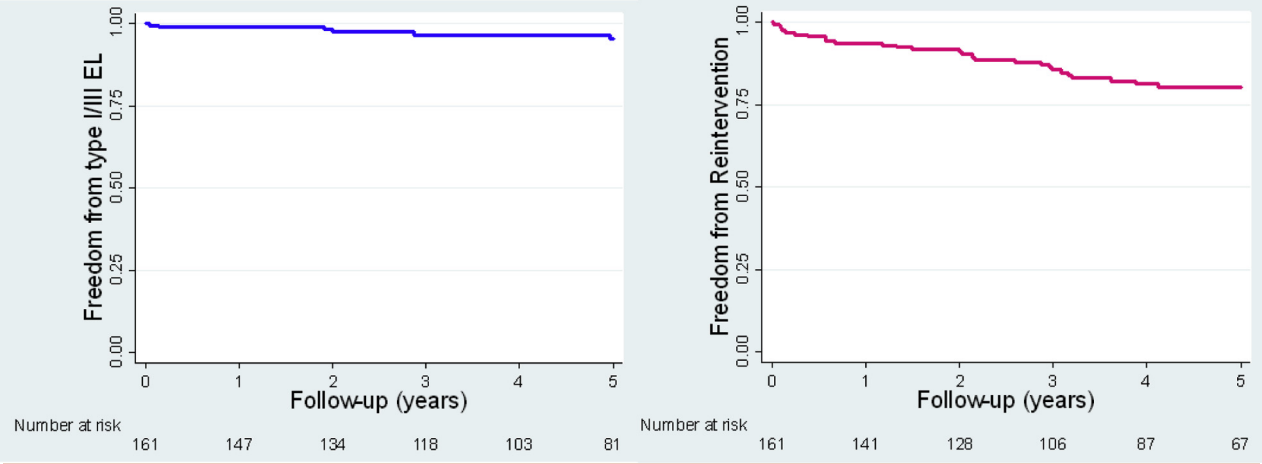

Fig 2. Freedom from type I or type III endoleak (*EL*), migration, and reintervention.

trials.[15-17] The 5-year freedom from all-cause (75%) and aneurysm-related (99%) mortality was consistent with prior EVAR trials.[19,21,35,36] Given that only patients with straightforward anatomy as far as neck length and access vessel diameter were enrolled in these trials, the long-term mortality rates of the Ovation trial are encouraging and support its use in patients with challenging aortoiliac anatomy. Because one of the main challenges with EVAR is patient ineligibility because of difficult aortic anatomy, the ability to treat a wider range of patients without sacrificing long-term treatment durability is the most important study finding. In one study of >10,000 EVARs performed in the United States, up to 58% of patients did not meet the most conservative IFU guidelines. These patients had more sac expansion than patients who underwent the procedure with appropriate anatomy.[11]

Even with the positive results in this study, some issues with the Ovation graft have been reported in the literature and warrant further discussion. There have been a few reports of a systemic and temporary hypersensitivity reaction with the Ovation graft.[37,38] Although uncommon, such reactions are possible because of inadvertent disconnection between the delivery catheter and aortic body or in cases of polymer overfilling. Others have encountered technical challenges during deployment of the Ovation graft related to difficulty in cannulating the contralateral limb gate.[39] All of the underlying causes of these challenges with the Ovation graft have been identified and addressed with next-generation Ovation stent grafts.

The primary strength of this trial is the generalizability of long-term results among different geographies and across a wide range of aortic anatomies. A limitation of this study was the nonrandomized design with no concurrent control group. As such, comparisons of trial results with those from other EVAR or surgical studies may be confounded by differences in patient characteristics, trial conduct, stent graft performance, or other factors. Also, only 67% of patients returned for a 5-year

Table IV. Patients requiring reintervention

Indication for reintervention	Patients (N = 161), No. (%)
Type II endoleak	17 (10.5)
Limb occlusion or stenosis	7 (4.3)
Type IA endoleak	4 (2.5)
Type IB endoleak	1 (0.6)
Aortic body stenosis	2 (1.2)

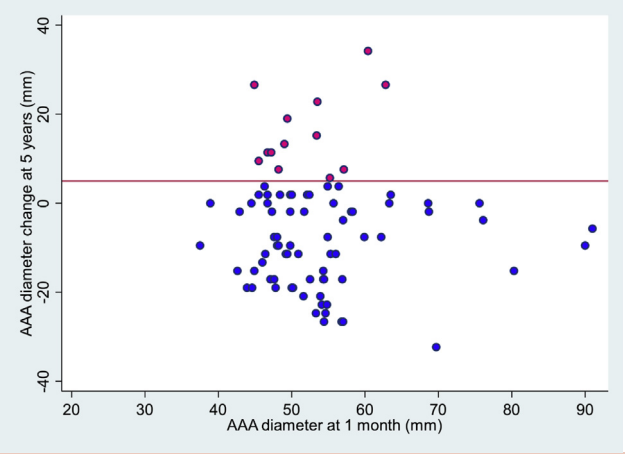

Fig 3. Scatterplot of change in abdominal aortic aneurysm (*AAA*) diameter at 5 years relative to the 1-month baseline.

follow-up visit. Whereas this rate is comparable to that of other studies, the smaller sample size in later follow-up decreases the precision of the long-term event rates.

CONCLUSIONS

Five-year results from the Ovation pivotal IDE trial demonstrate excellent long-term durability of this endograft despite challenging anatomy in 41% of the patients. There were no migrations or conversions to open repair, 95% freedom from type I and type III endoleak, and 99% freedom from aneurysm-related mortality. These results suggest that the Ovation stent graft may play an important role in expanding EVAR eligibility.

AUTHOR CONTRIBUTIONS

Conception and design: AB, AM, MM, TN, FV, MBM
Analysis and interpretation: AM
Data collection: Not applicable
Writing the article: AB, AM, MBM
Critical revision of the article: AB, AM, MM, TN, FV, MBM
Final approval of the article: AB, AM, MM, TN, FV, MBM
Statistical analysis: AM, AB
Obtained funding: Not applicable
Overall responsibility: AB

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Submitted Nov 1, 2019; accepted Jan 31, 2020.

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Supplementary Table (online only). Comprehensive list of secondary interventions

Days from implantation	Indication	Secondary intervention
5	Limb occlusion	Treatment NOS
29	Limb stenosis	Stenting
35	Type II endoleak	Coil embolization lumbar artery
40	Type IA endoleak	Balloon angioplasty of main body
51	Type IA endoleak	Coil embolization
87	Limb occlusion	Thrombolysis
138	Aortic body stenosis	Angioplasty and stenting
155	Type IB endoleak	Iliac extension
207	Type II endoleak	Coil embolization lumbar artery
210	Type II endoleak	Coil embolization lumbar artery
245	Aortic body stenosis	Angioplasty and stenting
430	Type II endoleak	Coil embolization lumbar artery
483	Limb occlusion	Stenting
542	Type II endoleak	Coil embolization lumbar artery
542	Type II endoleak	Coil embolization lumbar artery
716	Type II endoleak	Coil embolization lumbar artery
730	Type IA endoleak	Palmaz stent
738	Type II endoleak	Direct thrombin injection
758	Type II endoleak	Coil embolization lumbar artery
782	Type II endoleak	Treatment NOS
791	Limb occlusion	Thrombectomy and stenting
792	Type II endoleak	Treatment NOS
947	Type II endoleak	Coil embolization lumbar artery
1052	Type II endoleak	Treatment NOS
1055	Type II endoleak	Coil embolization lumbar artery
1083	Type II endoleak	Coil embolization lumbar artery
1092	Type II endoleak	Coil embolization lumbar artery
1130	Type II endoleak	Direct thrombin injection
1156	Type II endoleak	Coil embolization IMA
1161	Type II endoleak	Coil embolization lumbar artery
1168	Type II endoleak	Coil embolization lumbar artery
1196	Type II endoleak	Coil embolization lumbar artery
1251	Type II endoleak	Treatment NOS
1322	Limb occlusion	Femoral-femoral bypass
1416	Limb occlusion	Femoral-femoral bypass
1506	Type II endoleak	Direct thrombin injection
1526	Type II endoleak	Coil embolization lumbar artery
1806	Type IA endoleak	Aortic cuff

IMA, Inferior mesenteric artery; *NOS*, not otherwise specified.