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ORIGINAL ARTICLE

Treatment of abdominal aortic aneurysm with a new type of polymer-filled low profile device

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ABSTRACT

Purpose of the study: To evaluate the mid-term safety and effectiveness of a novel stent graft for treatment of abdominal aortic aneurysm (AAA).
Methods: Thirty-three patients with AAA (20 males and 13 females; mean age: 71.3 y) were treated with the Ovation™ Abdominal Stent Graft System (TriVascular, Inc., Santa Rosa, CA, USA). Indications for endovascular aneurysm repair: AAA $\geqslant$5.5 cm, neck $\geqslant$7 mm, angulation $\leqslant$60° and with an inner wall diameter of no less than 16 mm and no greater than 30 mm; the presence of neck calcification and thrombosis is not much of a problem in this device because aortic seal is achieved with 2 polymer-filled sealing rings and the fixation by means of a suprarenal stent with 8 pairs of anchors. Patients were followed through discharge and returned for follow-up visits. The follow-up protocol included a CT-A exam at 1 and 12 months after the intervention; the mid-term follow up was performed at 3 and 6 months with contrast-enhanced ultrasound (CEUS). Mean follow-up duration was 18.6 months (range: 3–25 months).
Main findings: Technical success was 100%. Mean implantation procedure time was 31.1 minutes, and median hospital stay was 4.6 days. None of the patients required conversion to open surgery, and no aneurysm enlargement, rupture, fracture, or migration were observed. No type I, III or IV endoleaks were observed. Hospitalization death rate was 0%. Death rate at 30 days was 0%. No major complications were observed.
Conclusions: The first results from this 3-center study with the Ovation stent graft are promising with high technical success and excellent safety and effectiveness.

1. Introduction

Endovascular aneurysm repair (EVAR) is a widely embraced minimally invasive alternative to open abdominal aortic aneurysm (AAA) repair. EVAR is associated with less blood loss, shortened hospital stay, early mobility, and fewer earlier adverse events. [1] It is current practice in many centers to reserve standard open infrarenal AAA repair for patients with unsuitable anatomy for EVAR and for younger patients with few comorbidities and good life expectancy. Typical anatomical criteria for EVAR include, aortic neck length of at least 10–15 mm, neck diameter not exceeding the device recommendations, neck angulation less than 60° and adequate iliac artery diameter for delivery of the device. [2] EVAR of AAAs not fulfilling one or more of the above anatomical criteria for the neck is associated with an increased incidence of type I endoleak, migration of the endograft and aortic neck dilatation. Furthermore, anatomically smaller iliac arteries (such as in short females) where iliac diameter may be less than 1 cm or in patients with concomitant iliac occlusive disease causing iliac artery stenosis with a residual lumen between 5–8 mm are usually excluded from EVAR with conventional devices.

The Ovation™ Abdominal Stent Graft System (TriVascular Inc, Santa Rosa, CA, USA) is a novel endoprosthesis that was designed to overcome the limitations of current endografts by accommodating a broad range of aortic morphology and by utilizing an enhanced seal mechanism that may potentially reduce the risk of endoleak and sac enlargement.

The aim of this study was to demonstrate the technical success, mid-term safety and effectiveness of the Ovation device for treatment of a series presented in a contemporary, real life (realistic) setting.

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Table 1
Patient baseline characteristics

Patient	Characteristic[a]							
	D2	D3	D6	D7	D8	D9	N1	N2
1	17.6	24.9	11	12.3	9.3	12.4	10	42
2	17.8	24.1	9.7	10.9	12.9	12.3	12	5
3	22.5	23.5	16.1	16.0	15.3	15.4	9	0
4	23.0	24.4	15.5	16.2	15.2	16.0	7	21
5	24.6	26.6	12.8	13.2	14.2	15.2	7.5	0
6	24.4	26.5	17.0	18.9	12.2	12.6	8	51
7	20.5	25.0	15.0	17.5	16.0	12.8	12	0
8	22.0	23.5	10.0	15.0	14.0	13.2	7.5	41
9	22.0	22.7	40.2	10.8	16.3	14.6	8	60
10	21.6	23.7	22.4	14.5	12.6	13.6	12	0
11	24.1	25.9	8.8	7.7	15.7	10.2	12	24
12	19.45	20.8	17.0	12.1	14.75	10.4	10	10
13	24	24	15	14	14	13	9.5	35
14	24	24.5	16.5	14	17	12.5	8	0
15	25.5	27.5	21	16.5	20	15	7	0
16	28.2	29	17	14.5	15.5	11.5	7.5	20
17	29	30	14	10	13	8.5	12	15
18	30	32	12	12.5	10	9	13	40
19	19	20	18	17.5	17	12	8	0
20	25	27	16	13.5	14	12.5	7.5	0
21	29	29	17	15	16	13.5	12.5	20
22	23.5	25	19	18.5	17	15	10	40
23	26.5	27	14	12	15	14.5	9.5	0
24	28	29	23	14	20	16.5	8	20
25	27	30	21	15.5	19	17	7.5	42
26	30	34	13	12	13.5	13	15	5
27	19	24	23	12.5	24	14	10	58
28	19.5	23	21	13	18	15	7.5	21
29	23	25.5	16	14	15.5	12	9	0
30	22.5	26.5	12	12	16	14	8.5	51
31	26	30	17	15	21	16	7	0
32	24	27	18.5	16	19	17	7	41
33	22.5	24	14	12	14	13.5	7	60

[a] Abbreviations:
D2 (mm): Aortic diameter at lowest renal artery (or intended landing zone)
D3 (mm): Aortic diameter + 13 mm (distal to D2 measurement)
D6 (mm): Right mid (at mid common iliac artery)
D7 (mm): Right distal (~0.5–1 cm proximal to hypogastric origin)
D8 (mm): Left mid (at mid common iliac artery)
D9 (mm): Left distal (~0.5–1 cm proximal to hypogastric origin)
N1 (mm): Proximal neck length (from lower renal artery to beginning of dilatation)
N2 (°): Proximal neck angulation (between proximal neck and aortic dilatation)

2. Patients, methods and materials

2.1. Patients

All participants gave informed consent according to the practice in 3 institutes. Patients presented with an AAA requiring intervention and with aorto-iliac characteristics suitable for treatment with the Ovation device. Patient baseline characteristics are presented in Table 1. This retrospective 3-center study involved 33 patients who were treated with the TriVascular Ovation device between December 2010 and March 2013. Patients were followed through hospitalization and returned for regular follow-up visits, with contrast-enhanced CT scans performed at 1 and 12 months after the intervention. Mid-term follow up was performed at 3 and 6 months with contrast-enhanced ultrasound (CEUS) and if an endoleack was detected then a contrast CT scan was also performed.

2.2. Baseline imaging and treatment procedure

All patients underwent preoperative evaluation of their aneurysm with conventional contrast-enhanced CT imaging with thin (1 mm) slice thickness and with intravenous administration of iodinated contrast media.

The arterial phase was acquired after the administration of 120 ml of 350 mg I/ml iodinated contrast media (Iomeron 350, Bracco, Milan, Italy; Visipaque 320, GE Healthcare, USA) at an injection rate of 4 ml/s, followed by 40 ml of saline solution at the same injection rate. Optimal arterial enhancement was achieved using the bolus tracking