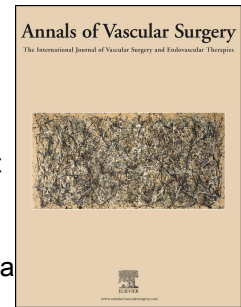


Accepted Manuscript

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PII: S0890-5096(16)30848-2

DOI: [10.1016/j.avsg.2016.06.033](https://doi.org/10.1016/j.avsg.2016.06.033)

Reference: AVSG 3018

To appear in: *Annals of Vascular Surgery*

Received Date: 29 April 2016

Revised Date: 17 June 2016

Accepted Date: 23 June 2016

Please cite this article as: Siani A, Accrocca F, De Vivo G, Mounayergi F, Siani LM, Antonelli R, Anaphylactic reaction during implantation of Ovation Abdominal Stent Graft in patient with Abdominal Aortic Aneurysm, *Annals of Vascular Surgery* (2016), doi: 10.1016/j.avsg.2016.06.033.

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Anaphylactic reaction during implantation of Ovation Abdominal Stent Graft in patient with Abdominal Aortic Aneurysm.

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Congresses: no

Funding: no

Conflicts of interest: no

Acknowledgements: no

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ABSTRACT:

The Ovation Abdominal Stent Graft System is a trimodular endoprosthesis planned to overcome the limitations of currently available stent grafts, allowing through complex iliac and femoral access and providing a proximal seal in challenge infrarenal neck morphology. The proximal sealing is achieved by means of a network of inflatable rings filled with low-viscosity radiopaque polyethylene glycol (PEG) based polymer during stent graft deployment. The leakage of polymer outside the channel to fill the rings into the vascular system may induce an hypersensitivity reaction and anaphylactic shock. We report a case of anaphylactic reaction during Ovation Abdominal Stent Graft System implantation. The endovascular procedure was successfully concluded.

Keywords:

Abdominal aortic aneurysms, Ovation, anaphylactic reaction

Introduction:

Endovascular aneurysm repair (EVAR) is the preferred intervention for morphologically suitable abdominal aortic aneurysms (AAA) reducing early and mid-term mortality and morbidity⁽¹⁾. Although, more than 30% of patients with AAA are not suitable for EVAR due to challenging aortoiliac anatomy such as short and complex proximal neck seal zones and narrow, tortuous or angulated iliac vessels^(2,3). The Ovation Abdominal Stent Graft System (Trivascular Inc, Santa Rosa, CA, USA) is a new device with a main body delivered by the smallest commercially available, flexible, hydrophilic coated 14 F catheter, designed to overcome the limitations of currently available stent grafts, allowing through small and complex iliac and femoral access and providing a proximal seal in complex infrarenal neck morphology. In order to achieve the proximal sealing, a network of inflatable rings is filled with low-viscosity radiopaque polyethylene glycol (PEG) based polymer during stent graft deployment. The leakage of polymer outside the channel to fill the rings into the vascular system may cause hypersensitivity reaction and anaphylactic shock.

64 We present a case of severe anaphylactic reaction during implantation of the Ovation Abdominal
65 Stent Graft System successfully treated.

66

67 **Case Report:**

68 A 78 year old man was admitted to our department with severe back pain and AAA. His medical
69 history revealed hypertension, diabetes mellitus, coronary arteries disease, previous coronary
70 angioplasty. No know allergies were reported and laboratory studies were within normal references
71 values. CTA showed a 5.3 cm AAA without rupture (Fig 1). Owing to angulated and small diameter
72 iliac arteries, EVAR was performed with a 26 mm OVATION™ Abdominal Stent Graft
73 (Trivascular Inc, Santa Rosa, CA, USA) through bilateral percutaneous femoral approach under
74 local anesthesia with Prostar XL System (Abbot Vascular, Santa Clara, CA, USA). Guidewires
75 were placed in the aorta and endoprosthesis implant and deployment procedure were carefully
76 carried out according with instruction for use such as in our previous series of 72 cases in the last 2
77 years. The main body was deployed through the right side. No adverse reactions occurred during
78 the angiography and systemic heparinization. During polymer infusion of the inflatable rings,
79 patient reported an acute back pain and rapidly become unconsciousness with hypotension(from
80 140 to 60 mmHg) and tachycardia. At angioscopy the rings were incomplete filled after 6 ml of
81 polymer administration (Fig 2 A). The polymer loading was immediately interrupted and patient
82 resuscitated by means of laryngeal mask, massive fluid therapy with colloid solution and standard
83 therapy for anaphylactic reaction. No signs of rupture were detected at angiography but rings were
84 completely empty of polymer. Because of hemodynamic stability, the endovascular procedure was
85 completed. The right iliac limb, 16 mm in diameter and 120 cm in length, was deployed. The left
86 main body limb was engaged and crossed, through contro lateral approach, with 0.035 soft tip
87 guide wire over 5 FR Contra catheter (Terumo Europe, Leuven, Belgium). The guide wire was
88 recovered by means of 15 mm working diameters single helical loops snare (Micro Elite
89 snare, Vascular Solution Inc., Minneapolis ,USA) placed in aorta through left introducer sheath

(Fig 2 B). After 0,035 inch 260 cm long superstiff guidewire placement (Amplatz, Boston scientific, MA, USA), left iliac limb, 14 mm in diameter and 120 cm in length, was implanted. A kissing balloon angioplasty with ATLAS 12 x4 cm (BARD, peripheral vascular Inc, AZ, USA), to achieve a good sealing between the main body and iliac limbs was carried out. At control angiography aneurysm was successfully excluded and no type I or III endoleaks were observed (Fig 2 C). A CTA scan was performed after 2 days and no endoleaks were detected (Fig 3). Postoperative course was normal. Patient was discharged after 7 days. CTA performed at 1 and 6 months was normal.

Discussion:

The Ovation Abdominal Stent graft system is a trimodular device with an aortic body composed of low permeability PTFE graft with suprarenal nitinol stent and anchor for active fixation. Aortic body contains a network of inflatable sealing rings filled with low viscosity PEG based polymer that conforms to aortic neck of various shapes and provides proximal sealing. The iliac limbs are composed of nitinol stents encapsulated with low permeability PTFE that allow access in iliac arteries as small as 4.7 mm. EVAR with Ovation stent graft results in excellent 1 year results with AAA and all cause related mortality of 0.6 % and 2.5% respectively and 0.6% of AAA enlargement rate^(4,5,6). The fill polymer is composed of 3 components that are mixed prior to injection. PEG based polymer was chosen because it is non thrombogenic, bio compatible and non embolic. PEG was approved after rigorous bio compatibility testing required by the international standard on biocompatibility (ISO 10993-1) and these results were evaluated in order to achieve Conformitee Europeenne (CE) Mark and FDA approval⁽⁷⁾. Although polyethylene glycol (PEG) can lead to complement activation with hypersensitivity and anaphylactic response as reported with commercial PEG containing contrast used for echocardiography⁽⁸⁾. Currently to our knowledge, only one case of anaphylactic reaction due to polymer leakage into

116 bloodstream was reported by Sfyroeras et al⁽⁹⁾. The author report such the endovascular procedure
117 was abandoned without trying to implant the limbs because of severe hemodynamic instability.
118 Moreover patient, after 4 months, refuse any treatment . Although , according with data from FDA
119 database about all retrieved reports concerning the Ovation stent graft from 2012 to 2015, 15
120 reported cases of leak of polymer fill into vascular system really occurred. The majority of events
121 were observed in 29 mm aortic body stent graft. None of this patients died and procedure was
122 interrupted due to severe hemodynamic instability in 3 of 16 cases without iliac limbs grafts
123 deployment and AAA exclusion. In all cases the cause was not identified and attributed to
124 technical error of polymer kit, difficulties in advancing the stent graft or tension before
125 repositioning the endograft that could be compromised the delivery system connection with
126 polymer leakage^(9,10). In our case , no specific test was carried out to confirm the diagnosis of
127 anaphylactic reaction and diagnosis and treatment was based on clinical criteria. In case of
128 incomplete filling of the aortic body graft some strategies can be planned intraoperatively to
129 achieve a safe proximal seal and engage the contralateral limb . In our case we perform a prompt
130 stabilization of main body by means of right iliac limb deployment, retreating the superstiff
131 guidewire to avoid the tension on the aortic body . Contralateral main body limb can be engaged
132 through brachial or contralateral approach. In our case , we preferred a contralateral approach using
133 a soft tip guidewire to avoid the kinking of the limb due to low columnar force of main body leg
134 due to failure of polymerization and lack of nitinol support. After deployment of contralateral iliac
135 limb, a kissing balloon angioplasty with non compliant balloon was carried out to achieve a good
136 sealing between main body and iliac limbs , avoiding the risk of type III endoleak. The major
137 concern after incomplete polymerization of the rings still remains the proximal sealing. In our
138 case , we have a favorable anatomy with proximal aortic neck 22 mm in diameter and 35 mm in
139 length. We used a 26 mm Ovation stent graft and the over-sizing probably allowed to achieve a
140 good sealing during control angiography and follow up. Furthermore suprarenal stent with anchors
141 for suprarenal fixation lead to neck protection , avoiding the displacement of main body also in

142 cases of rings dysfunction.⁽⁶⁾. In our case no secondary endovascular procedure was needed and we
143 preferred a close follow up . Although several strategies have been suggested to treat type I
144 endoleak detected at control angiography or to prevent type I endoleak in cases of short proximal or
145 angulated neck . The use of Palmaz stent(Cordis Endovascular,Warren, NJ),that promote the
146 apposition of the graft to the aorta, seems to be a safe and effective approach and does not appear to
147 compromise durability of this procedure , despite patients requiring adjunctive Palmaz stent
148 placement are likely to be at high risk for subsequent graft-related events⁽¹¹⁾. Use of proximal cuff
149 or aortouniliac stent graft deployment could be interesting options to achieve a safe and durable
150 proximal sealing , but few experiences were reported in literature ⁽¹²⁾ .
151 Open conversion can be extremely demanding because the endograft is incorporated into aortic
152 wall. Some authors suggest that the design of the endograft and its proximal sealing allowed the
153 partial preservation of the graft and its use for proximal anastomosis ^(13,14) . To prevent this
154 complication we believe that a more caution during pullback of endoprosthesis and tension free
155 release are needed. Moreover , according with De Donato et coll. , we believe that the syringe must
156 be prudently loaded with only the exact amount of polymer necessary (for 26 mm= 9 ml) checking
157 the polymer infusion carefully under continuous angioscopy⁽¹⁵⁾. In our opinion the interruption of
158 procedure must be avoided and after hemodynamic stabilization it would be better to finish the
159 procedure. To avoid any medical claims, in our opinion, vascular surgeons should be aware of this
160 rare complication and inform patients of the possibility of rare anaphylactic reactions that is still an
161 unpredictable.

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220

221

222 Fig 1: Preoperative CTA showed 5.3 Abdominal aortic aneurysm.

223

224 Fig 2: Intraprocedural angiography showing that the rings were incomplete filled after 6 ml of
225 polymer administration at angioscopy (A).Controlateral left main body limb was engaged and
226 crossed , through controlateral approach, with 0.035 soft tip guide wire over 5 fr Contra catheter
227 (B). Aneurysm was successful excluded and no type I or III endoleaks were detected

228

229 Fig 3. CTA performed at 1 moths was normal. No type I or III endoleaks were detected .The
230 inflatable rings of endograft do not contain polymer .

