



## Correspondence

## Rationale for a new registry on EVAR: The EXTREME study



## H I G H L I G H T S

- Long term result after EVAR for AAA are still considered one of the main limits to the application of this treatment.
- According with IFU and guidelines, EVAR still has several anatomical limitation.
- Ovation Stent-Graft is an unique devices allowing to implement the range of patients amendable to be treated by EVAR.

## A B S T R A C T

## Keywords:

AAA  
Ovation stent-graft  
Challenging anatomies  
IFU

To report rationale of a physician-initiated study: Expanding Indications for Treatment with Standard EVAR in Patients with Challenging Anatomies, a Multi-Centric Prospective Evaluation - EXTREME.

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Endovascular aneurysm repair (EVAR) has become the treatment of choice for abdominal aortic aneurysms (AAAs) [1,2]. Nowadays, the most important limit to the effectiveness of this technique is represented by complex anatomical situations, especially regarding the morphology of the proximal sealing zone [3]. In previously published experiences, the use of EVAR outside the devices specific instruction for use (IFU) in patients with challenging proximal aortic necks yielded a not negligible rate of immediate complications and reinterventions [4].

In a previous experience, the presence of a challenging proximal aortic neck was associated with a higher rate of reintervention in the first month after EVAR, even if this difference was lost during the follow-up [5]. Obviously, the use of branched or fenestrated endografts may be a suitable alternative to standard EVAR in patients with challenging necks. Unfortunately, an increase in costs, compared to standard grafts, and a non-negligible risk of reintervention due to branch-related complications should be accounted [6]. So, we are far from to the optimum ideal solution, but we strongly believe that in absence of high quality evidences, the simplest option should be considered the best available option.

In last years, two new concept-devices based on polymer-obtained sealing have become available for AAA treatment: Ovation stent-graft, and Nellix device (both from Endologix, Irvine, CA - USA).

The Nellix endosystem (Endologix, Irvine, CA) was developed for Endovascular Aneurysm Sealing (EVAS). The graft uses polymer-filled polyurethane endobags surrounding balloon-expandable stent-frames covered with expanded polytetrafluoroethylene. A such designed graft, theoretically, stabilizes the aneurysm sac by completely filling the aortic cavity as well as eventual concomitant iliac artery aneurysms. All those to reduce, or better to eliminate,

occurrence of type I and type II endoleaks, and stent-graft migration. Moreover, the single-piece design for the individual right and left device eliminates the threat of component separation and type III endoleaks [7]. Also the Ovation endograft represents a new technical step in EVAR [8,9]. This new device separates fixation from sealing: fixation is guaranteed by suprarenal stent and anchors, while sealing is ensured by inflatable rings filled with a low-viscosity, non-embolic, radiopaque fill polymer. The presence of the polymer-filled network also allows the graft to conform to the patient's aortic neck, providing a precise and reliable sealing in a great variety of anatomies [10]. Different from common stent-graft platforms, separation between fixation and sealing ensures that in the Ovation endograft stent and fabric do not compete for the same space within the shaft and an ultra-low-profile delivery systems can be achieved (14–15F outer diameter for the main body, and 12–15F for the iliac limbs), allowing to treat patients presenting a wide range of iliac access [11].

The Ovation stent-graft safety, increasing the range of AAAs suitable for standard EVAR procedures as reported in several (although limited) series, promises to be the best available options [10–12].

With the aim to confirm those results in a larger, multicenter, and coordinated series, a new physician-initiated study has been designed: **Expanding Indications for Treatment with Standard EVAR in Patients with Challenging Anatomies, a Multi-Centric Prospective Evaluation – EXTREME (Appendix A)**. The objective of the EXTREME is to report the 30-day and 12-month technical and clinical success with endovascular repair using the ultra-low-profile Ovation Abdominal Stent Graft Platform in patients judged out of IFU for conventional bifurcated endografts, while amendable to treatment inside the IFU by Ovation stent graft (proximal aortic landing zone with an inner wall diameter of no less than 16 mm

and no greater than 30 mm at 13 mm below the inferior renal artery).

Investigators have planned to enroll a minimum of 100 patients in a year from the recruitment start (March 2017) and to collect clinical and anatomical data at baseline, hospital discharge, 1-month, and 12-month follow-up, in a prospectively compiled database.

Clinical endpoints are: freedom from AAA-related mortality, procedural-related serious and non-serious adverse events, AAA enlargement ( $\geq 5$  mm), and AAA rupture. While technical endpoints are: procedural success (complete delivery and deployment of one aortic body and two iliac limbs), access-related vascular complications, freedom from Type I and III endoleaks, freedom from graft migration ( $\geq 5$  mm), conversion to open repair, and all AAA-related secondary interventions. To avoid any potential inter-pretation bias, all CTA (preoperative, and post-operative 1-month, and 12-month scans) will be collected and sent for blind reading by a centralized core laboratory (Vascular and Endovascular Surgery, “Sapienza” University of Rome).

Aim of the EXTREME is to confirm the hypothesis that extremely challenging aortic anatomies could be effectively treated using a “non-conventional” off-the-shelf endografts, and avoiding technical and clinical issues, as well as higher costs, associated with fenestrated and branched devices.

#### Ethical approval

Not applicable.

#### Sources of funding

None.

#### Author contribution

Study Design and paper writing: Pasqualino Sirignano, Wassim Mansour, Laura Capoccia, and Francesco Speziale.

#### Conflicts of interest

None.

#### Guarantor

Francesco Speziale.

#### Research registration unique identifying number (UIN)

Not applicable.

#### Appendix A. EXTREME study group

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