Multicenter Italian Results With The Ovation Endograft For EVAR: Advantages And Limitations: From The EXTREME Trial

Francesco Speziale, Laura Capoccia

Conflict of Interest

I have nothing to disclose

ESVS Guidelines

Available guidelines recommend to perform EVAR in patients presenting at least a suitable Aortic Neck length >10mm

Debatable, maybe too restrictive

“Sapienza” Experience

We believe that some challenging necks could be effectively managed by EVAR

“Sapienza” Experience

No significant difference in immediate results between patients treated in and out IFU.
Satisfactory outcomes were maintained during 2 years of follow-up

New possibilities

If conventional endografts guarantee satisfactory results... could new devices further expand EVAR indications?
New possibilities

Pushing forward the limits of EVAR: new therapeutic solutions for extremely challenging AAAs using the Ovation® Stent Graft

Sirignano P, Capoccia L, Menna D, Mansour W, Speziale F
Journal Cardiovascular Surgery 2016

New possibilities

Real life experience with Ovation stent-graft: lesson learned from first one-hundred-fifty treated patients

AVS 2017

Our single-center experience suggests that EVAR by Ovation stent-graft can be performed with satisfactory immediate and mid-term outcomes in patients presenting severe challenging anatomies

Moving from those promising experiences, a new registry was started, aiming to demonstrate the feasibility of EVAR by Ovation implantation in challenging anatomies

A new Registry

Expanding Indications for Treatment with Standard EVAR in Patients with Challenging Anatomies, a Multi-Centric Prospective Evaluation – EXTREME

Sirignano P, Speziale F et al. AMS 2017

Study Design
Prospective, consecutively-enrolling, non-randomized multicenter post market registry.

Study Population
At least 60 patients

Safety and Efficacy
Clinical endpoints
- Freedom from AAA-related mortality
- AAA enlargement
- AAA rupture

Technical endpoints
- Access-related vascular complications
- Technical Success
- Freedom from Type I & III endoleaks
- Migration
- Conversion to open repair
- Re-interventions
Extreme Registry

Between March 2017 and March 2018, 122 patients were enrolled across 16 centers in Italy and Spain.

Demographic Characteristics

Total Patients 122

| Age (mean ± SD) | 78.65 ± 7.67 |
| Male Sex (n%;%)  | 111; 90.98    |
| Hypertension (n%;%) | 106; 86.88  |
| Dyslipidemia (n%;%) | 85; 69.67   |
| Diabetes (n%;%)  | 72; 63.93     |
| CAD (n%;%)       | 69; 56.55     |
| Smoking (n%;%)   | 83; 68.03     |
| COPD (n%;%)      | 67; 54.91     |
| CRI (n%;%)       | 45; 36.88     |
| PAOD (n%;%)      | 37; 30.32     |
| ASA III/IV (n%;%)| 32; 26.22     |

Anatomical Features

Mean Aortic Neck length was 7mm

All grafts were released according to IFU

Technical success 98.36%

2 Type Ia endoleaks
15 Type II endoleaks
1 Month Results

- No new Type Ia endoleaks
- 9 persistent Type II endoleaks
- 2 limb occlusions

Thanks to all Collaborators

PI: Francesco Speziale
Federico Accrocca, Stefano Bartoli, Stefano Campanini, Laura Capoccia, Simone Cuozzo, Gianmarco de Donato, Javier Martinez Gamez, Arnoldo Ippoliti, Gaetano La Barbera, Massimo Lenti, Nicola Mangialardi, Wassim Mansour, Rafael Gomez Medialdea, Claudio Novati, Giovanni Pratesi, Carlo Rivellini, Manuel Rodriguez Pinero, Sonia Ronchey, Carlo Salacci, Andrea Stani, Roberto Silingardi, Pasqualino Sirignano, Francesco Spinelli, Francesco, Talarico, Maurizio Taurino