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EXPANDED USE OF A NOVEL LOW PROFILE STENT GRAFT IN THE TREATMENT OF ALL THORACIC AORTIC SEGMENTS

Francesco Setacci, Martina Giambra, Massimiliano Veroux, Giuseppe Roscitano, Alessia Giaquinta, Maria Grazia Lumia, Perfrancesco Veroux
Vascular and Organ Transplant Unit, University Hospital of Catania, Catania, Italy

INTRODUCTION

Thoracic endovascular aortic repair (TEVAR) has modified radically the way most surgeons approach thoracic aortic pathology, either in acute or chronic settings [1-7]. At our institution we use TEVAR consistently as a first-line procedure in many instances, both acute and chronic. Many centers have a significant experience with most of the commercially available devices as a part of clinical trials or investigational studies [7], but only one stent-graft (RelayPro) received the Conformite´ Europeene mark (CE mark) and is therefore available for clinical use for all thoracic segments [8].

AIM

To report the outcomes of the expanded use of the RelayPro stent-graft in all the thoracic aorta in a high volume Italian vascular center.

Figure: 1: Terumo RelayPro deployment.

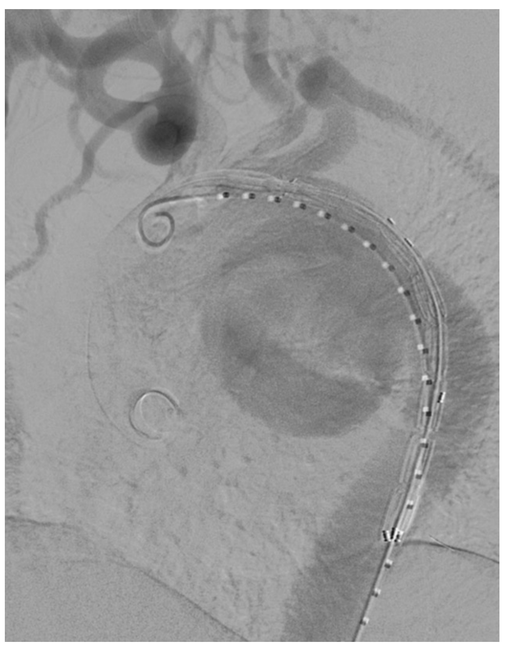
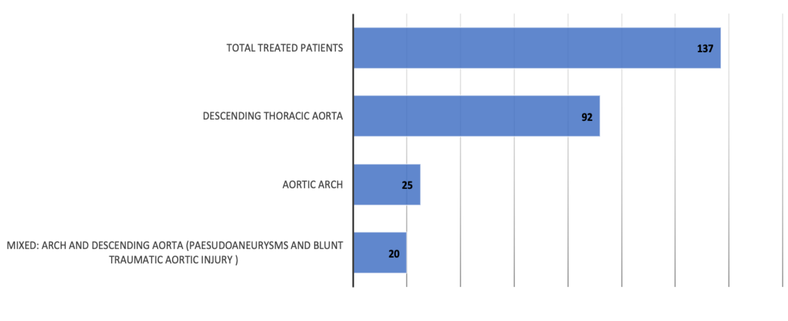


Figure 2: Localization of the treated disease



METHODS

This was a prospective, single center, observational study report the outcomes of all thoracic segments aortic diseases undergoing thoracic endovascular aortic repair (TEVAR). Inclusion criteria included all patient with anatomic findings suitable for TEVAR and treated with the RelayPro low-profile stent-graft (Terumo Aortic, USA) according with EU instructions for use . Primary safety outcomes of the study were the incidence of all cause death, major stroke and spinal cord ischemia at 30-day. Co-primary effectiveness endpoints were evaluated by assessing a composite of technical success, retrograde dissection, patency, absence of aneurysm rupture, type I/III endoleaks, endograft migration and reintervention at 30-day and 1 year. As secondary endpoints, we evaluated the confidence of RelayPro device in the treatment of aortic arch pathologies at 30-day and after 12 months. Raises the question if any were treated outside IFU. Perhaps not for the abstract but certainly to consider in the presentation and article

Table I: 30-day and 1-year primary safety and co-primary effectiveness outcomes in all aortic segments.

Primary Safety Outcomes	N=137 30-day	N=137 1-year
All-cause death, n (%)	4 (3.2)	4 (3.2)
Stroke, n (%)	1 (0.8)	1 (0.8)
Spinal cord ischemia, n (%)	0 (0.0)	0 (0.0)
Co-Primary effectiveness endpoints		
Technical Success, n (%)	137 (100)	/
Retrograde Dissection n (%)	0 (0)	1 (0.8)
Aneurysm Rupture, n (%)	0 (0)	0 (0)
Type I/III endoleaks, n (%)	0 (0)	(0)
Endograft Migration, n (%)	0 (0)	0 (0)
Reintervention, n (%)	0 (0)	0 (0)
Patency, number of grafts (%)	203 (100)	203 (100)

Table II: 30-day and 1-year secondary endograft effectiveness aortic arch outcomes.

Secondary effectiveness endpoints	30-day	1-year
Technical Success, n (%)	34 (100)	/
Patency, number of grafts (%)	52 (100)	52 (100)
Aneurysm Rupture, n (%)	0 (0)	0 (0)
Type I/III endoleaks, n (%)	0 (0)	0 (0)
Endograft Migration, n (%)	0 (0)	0 (0)
Reintervention, n (%)	0 (0)	1 (0.8)

RESULTS

From January 2019 to May 2023, 137 patients (107 men; mean age 67.75) underwent TEVAR with the last generation Relay Pro low-profile stent-graft (Fig.1).
Sixty-one (44.5%) presented atherosclerotic aneurysms (AS), 41 (29.9%) aortic dissection (AD) and 15 (10.9%) penetrating aortic ulcers (PAU). Blunt traumatic aortic injury and pseudoaneurysms were observed in the remaining cases (14.5%). Among all of them, 34 cases (24.8%) involved the aortic arch (hybrid procedure in 9.4% of the cases) while 103 cases (75.1%) affected the descending aorta (Fig. 1). The 34 arch morphologies were classified in [Z0 = 7 (20.5%), Z1= 8 (23.5%), Z2= 19 (55.8%)]. A total of 203 devices were implanted (52 devices in the arch).
Technical success rate was 100%. At 30-day, all-cause death, spinal cord and stroke were reported in 3.2% (4 patients with ruptured TAA), 0% and 0.8% of patients, respectively. No stent-graft occlusion, endograft migration, type I/II endoleak and aneurysm rupture were detected after 1-year (Table I). Analyzing the behavior of the stent-graft for the treatment of the aortic arch, technical success was achieved in all cases. Moreover, no stent-graft occlusion, endograft migration and aneurysm rupture were reported after 1-year (Table II)

CONCLUSIONS

The extended application of the low-profile RelayPro thoracic endograft met the primary and secondary endpoints of the study, demonstrating excellent safety at 30 days and effectiveness up to 1 year. Ongoing follow-up is in place to assess long-term outcomes and durability especially in the aortic arch.

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