New Single-Sided Access EVAR Device: The Horizon™ CE PIVOTAL study – Short-term Results

Objectives:
To investigate performance and safety of a new single-sided, 14Fr, bottom-up concept of endovascular stent grafts - the HORIZON™ for treatment of abdominal aortic aneurysms (AAA). The HORIZON™ AAA stent graft consists of three stent graft modules, each introduced separately (model 1 – iliac to iliac limb with optional iliac extension for the base limb, model 2 – primary aortic limb, model 3 – aortic extension limb). Data of this study will provide early information on clinical use of this emerging device.

Methods:
This is ongoing, prospective, non-randomized, open-label, one arm, interventional multi-center (nine countries participating) clinical study. Study population consists of twenty one (21) patients, age ≥18 years, diagnosed with infrarenal abdominal aortic and/or aortoiliac aneurysms who met inclusion criteria. Data are being collected at baseline, implantation, pre-discharge, 1, 6, 12 months and annually until completion of 5 years follow-up. All adverse events, including death, are recorded throughout the course of the study. The primary performance endpoint at one month post implantation was composite of successful delivery and pararenal deployment of the device, aneurysm isolation, endoleaks, stent graft occlusion, conversion to open surgery, aneurysm rupture, and clinically significant stent graft migration. The primary safety endpoint at one month post implantation was free of Major Adverse Events (MAEs). MAEs was defined as all-cause mortality, myocardial infarction, renal failure, respiratory failure, paraplegia, stroke, bowel ischemia and procedural blood loss ≥ 1000ml.

Results:
21 patients had been treated by complete three component system device, and two patients additionally received two more module 2 components. At one month follow-up 100% performance and 100% safety were obtained, with no endoleaks, aneurysm rupture, stent graft occlusion, stent graft migration, nor conversion to open surgery. There was one case of death due to myocardial infarction (unrelated to the device implantation) among three patients who have reached six months follow up.

Conclusion:
The HORIZON™ device presents new EVAR technology as a novel single sided access EVAR. This device potentially may offer the new alternative in AAA treatment. The endograft has met all safety and performance endpoints as implantation as well as very early follow-up results.

Professional Practice Gap:
Since the short follow-up presents temporary limitation, longer follow-up is required

Knowledge and/or Strategy:
As an single-sided access EVAR, this device potentially may offer the new alternative in AAA treatment.