ARTIGO ORIGINAL ORIGINAL ARTICLE

TOTAL AORTIC ARCH REPLACEMENT WITH E-VITA OPEN PLUS™ HYBRID PROSTHESIS – INITIAL EXPERIENCE FROM A SINGLE SURGICAL CENTER

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Abstract

Background: *Complex pathology of the Thoracic Aorta constitutes a challenge, needing a complex and multidisciplinary approach. The hybrid stent graft prosthesis E-vita OPEN PLUS™ avoids a two-stage surgical approach in the surgical treatment of complex thoracic aortic disease. The E-vita Open Plus™ is estimated to generate cost savings compared with current two-stage repair from about 2 years after the procedure.*

Methods: *Between February 2017 and July 2019, a total of 6 patients, underwent one stage surgery for treatment of multisegmental thoracic aortic disease with hybrid stent graft prosthesis E-vita OPEN PLUS™*

We collected the data from our records and compared them to the International E-vita Open Registry (IEOR), regarding ischemic and operative times as well as adverse events monitored during follow-up.

Results/Discussion: *The average patient age was 56 years (range: 36-76 years). The average Cardiopulmonary Bypass, Aortic Cross Clamping and Circulatory Arrest times where 204, 86 and 63 minutes respectively.*

The recovery after procedure had fewer complications and the length stay was less than described in literature. There was no in-hospital mortality.

In all patients there was a reduction of aneurysm sac size and positive aortic remodeling and all where asymptomatic in regard to cardiovascular symptoms.

Conclusions: *The use of E-vita OPEN PLUS™ seems a safe and efficient option for patients with complex aortic arch pathology. In our experience, surgery allowed treatment of extensive thoracic aortic diseases with satisfactory short- and mid--term results.*

INTRODUCTION

Type B aortic dissection (TBAD) with arch involvement (also called a non-A non-B aortic dissection) is a severe, life-threatening condition. By combining open surgical and endovascular techniques, the hybrid approach has emerged as the preferred treatment option for this challenging disease. The hybrid concept entails reimplantation or bypass of all epiaortic vessels to create an adequate proximal landing zone suitable for thoracic endovascular aortic repair (TEVAR). However, the outcome of patients with TBAD treated with complete surgical debranching in the native ascending aorta and subsequent TEVAR is unsatisfactory, resulting in a mortality rate of 27-70%.[1,2] Consequently, the therapeutic management of complicated TBAD by open arch replacement with Frozen Elephant Trunk (FET) placement is becoming the first line treatment in many leading centers for aortic surgery.

E-vita OPEN PLUS™ is one of the FET prosthesis available, it is a hybrid stent-graft system, used in the treatment of Aortic dissections Stanford type A, Complex Stanford type B, Aortic arch aneurisms and chronic extensive thoracic aortic dissections. Available evidence suggest that E-vita OPEN PLUS™ for treating complex aneurysms and dissections of the thoracic aorta could remove the need for a second procedure and the associated risk of serious complications.[3] The E-vita OPEN PLUS™ is estimated to generate cost savings compared with current two-stage repair from about 2 years after the procedure.[3]

METHODS

The purpose of this article is to present the initial experience of the CHVNG/E Cardiac Surgery Department in the use of the E-vita OPEN PLUS™ in the treatment of multisegmental thoracic aortic disease. Between February 2017 and July 2019, 6 patients underwent E-vita OPEN PLUS™ implantation in our department.

Surgery was performed with cardiopulmonary bypass, total circulatory arrest, moderate hypothermia (24ºC), Bretschneider's HTK anterograde or retrograde cardioplegia, selective anterograde cerebral perfusion and noninvasive neuromonitoring.

The selective bilateral anterograde cerebral perfusion was performed by direct cannulation of the arterial brachiocephalic trunk and the left carotid, with temporary occlusion of left subclavian artery. The perfusion was set to 10mL/kg/min @ 40-80mmHg and then adjusted accordingly the neuromonitoring.

Anesthetic management include noninvasive neuromonitoring in all patients using a Near Infrared Spectroscopy (NIRS): an INVOS® monitor is able to provide information about the regional oxygen saturation within the microcirculation. It is applied to the forehead and reflects the trend of median oxygen saturation of the frontal lobes bilaterally so we can access the quality of the anterograde selective cerebral perfusion in both sides, in real time. Bispectral Index (BIS) monitor was also used to access depth of anesthesia using electroencephalogram activity. This monitor can also act as a surrogate to access ischemia as electroencephalogram activity diminishes or even disappears when blood flow is insufficient or absent. We use the information provided by these monitors to adjust cerebral perfusion or detect any complication throughout the procedure.

We collected the data from our records and compared to the International E-vita Open Registry (IEOR) that was initiated in 2008 to study the principles of this treatment algorithm. The IEOR represents the first database to evaluate aortic disease after hybrid stent-grafts.

RESULTS

In the 30-month period 6 patients were submitted to the procedure. From the data collected from our records we produce 4 tables, in 2 of them we compare our results with the International E-vita Open Registry (IEOR). The Table 1 shows the baseline characteristics of our patients.

The indications were:
- Chronic Stanford type A aortic dissection (2);
- Multisegmental thoracic aneurysmal disease (3);
- Ascending aorta, aortic arch and right subclavian artery aneurism in tertiary syphilis.

Table 1 **Baseline characteristics of CHVNG/E and International E-vita Open Registry.[4]**

Baseline characteristics	CHVNG/E, Portugal		IEOR
	n patients	%	%
Age - (Mean ± SD)	56 ± 14		57 ± 13
Age > 70 years	1	17	17
Male	3	50	77
BMI (kg/m2) - (Mean ± SD)	24,5 ± 4.4		26 ± 4
ASA physical status ≥ 3	5	83	n.a.
Coronary artery disease	1	17	12
Ejection Fration < 60%	3	50	41
Previous cardiovascular surgery	3	50	36
Hypertension medication	4	67	78
Diabetes mellitus	1	17	5
Creatinine > 2mg/dL	1	17	13
Chronic Obstructive Lung Disease	1	17	20
History of Stroke	1	17	5
Loeys-Dietz Syndrome	1	17	n.a.
Syphilitic aortitis	1	17	n.a.

The mean and SD age of the patients was 56±14 years, 3 males and 3 females.

All where elective procedures: 2 of them were reoperations and 4 surgeries had concomitant procedures (aortic valve replacement, aortic prosthesis replacement and extra-anatomic bypass of aorta to right subclavian artery and right carotid artery, tricuspid valve repair).

Mean Cardiopulmonary Bypass (CPB), Aortic Cross Clamping (ACC) and Circulatory Arrest times where 204, 86 and 63 minutes respectively. There was no in-hospital mortality.

There was a patient that had an increase in creatine level after surgery but resolved with medical treatment, and did not require dialysis.

One of the patients had heparin resistance, so we had to administer Fresh Frozen Plasma (FFP) to maintain the Activated Clotting Time (ACT) above 400 seconds during CPB which justifies the greater range of FFP on Table 2.

We only gave red blood cells to one patient, all the other procedures did not require red blood cells transfusions.

One of the patients had his aneurysmal disease discovered when being studied for upper right limb paresthesia. The patient had an aneurysmal disease, due to syphilitic aortitis, involving ascending and aortic arch including brachiocephalic trunk (till distal segments of the right subclavian) and until emergence of left subclavian artery. Five months after the procedure where an extra anatomic bypass was made from the aorta to the right subclavian and carotid arteries (Figure 1) the patient maintained hypoesthesia in territory C6-T2 and distal brachial monoparesis grade 5, wrist dorsiflexion and finger grip grade 2, (that was the only peripheral neurologic complication considered on Table 2).

After discharge morbidity: we have one patient with endoleak type III with TEVAR correction with

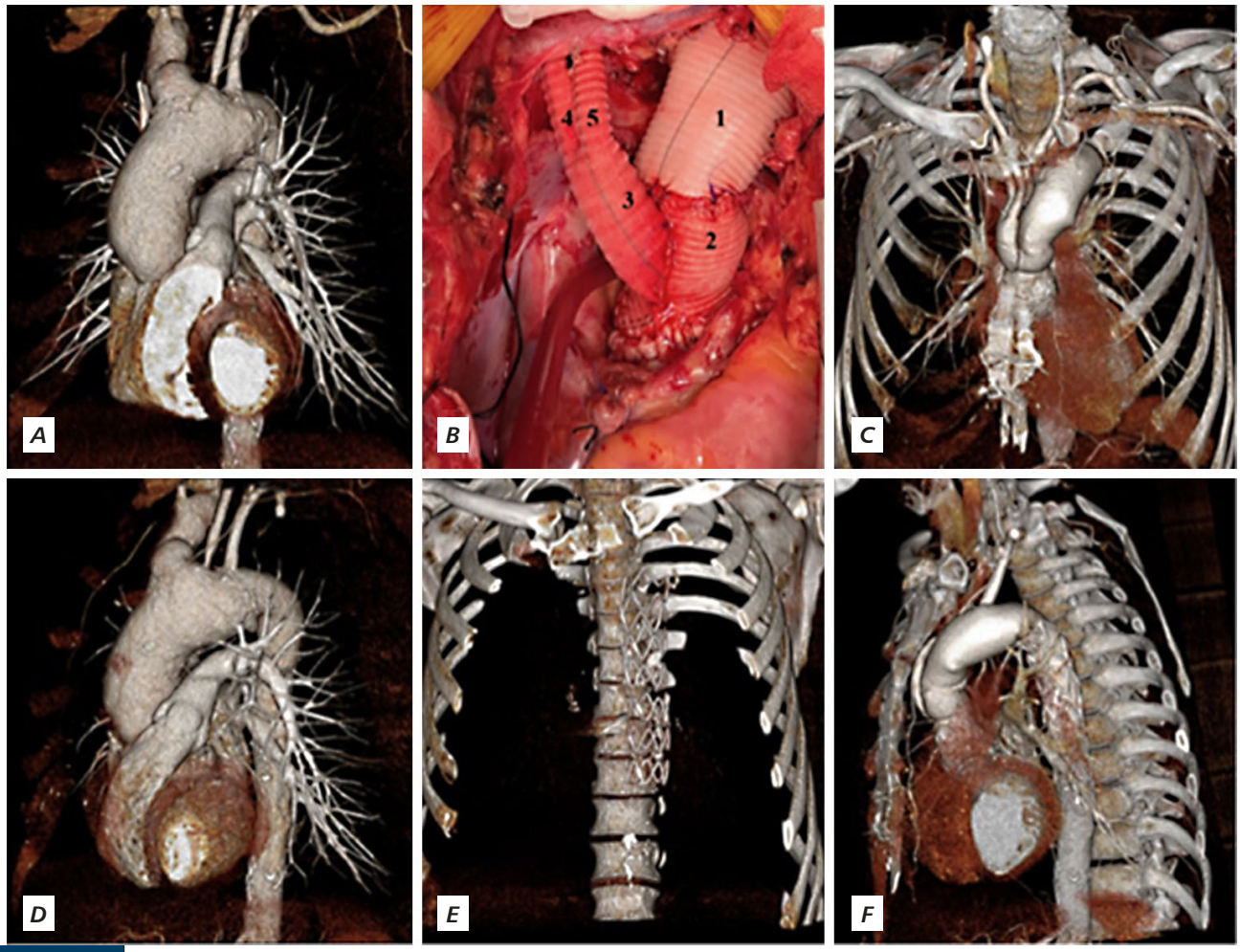

Figure 1

*Total arch replacement Evita Open Plus® #30 (1) + ascending aorta replacement Hemashield® #30 (2) + Aortic valve replacement SJM Regent® + extra-anatomic ascending aorta to right carotid and subclavian arteries Hemagard Knitted® #14*7 (3) + ligation of Innominate artery + island reimplantation of the right subclavian (4) and right common carotid (5) arteries.*
A and D – Preoperative computed tomography image showing ascending aorta and brachiocephalic trunk aneurysm due to syphilitic aortitis
B – Intraoperative photo showing extra anatomic bypass from the aorta to the right subclavian and carotid arteries
C and F – Postoperative computed tomography image showing surgical correction
E – Postoperative computed tomography image showing E-vita OPEN PLUS™ prosthesis

Table 2 **Surgical and postoperative characteristics**

Operative		Number	%
Indications	Aortic Dissection: Stanford Type A	2	33
	Aortic Dissection: Stanford Type B	1	17
	Aortic Aneurism	3	50
Concomitant surgery	CABG	0	0
	AVR	4	67
	None	1	17
Surgical data		**Minutes (mean)**	**Range**
Total Surgical time		429	(203-600)
Cardiopulmonary Bypass time		204	(135-310)
Aortic Cross Clamp time		86	(68-115)
Circulatory Arrest time		63	(22-82)
Blood Product usage		**Units (mean)**	**Range**
Red Blood Cell (250ml)		0.67	(0-4)
Fresh Frozen Plasma (200ml)		5	(2-11)
Platelets (60ml)		7	(0-14)
Fibrinogen		1.67	(0-4)
Prothrombin Complex Concentrate		0.33	(0-2)
Complications		**Number**	**%**
Supraventricular tachycardia		1	17
Recurrent laryngeal nerve palsy		0	0
Pleural effusion		0	0
Renal failure (acute, non-dialysis)		1	17
Peripheral neurologic complications		1	17
Pneumonia		0	0
ARDS		0	0
Stroke		0	0
Tracheostomy (prolonged ventilation)		0	0
Re-exploration		0	0
Readmission		1	17
Death		0	0
Length of stay		**Days (mean)**	**Range**
UCI		4	(3-6)
Total		**10**	**(6-18)**

CABG - Coronary Artery Bypass Grafting | AVR - Aortic Valve Replacement

subsequent low flow type II endoleak; and a pericardiocentesis for pericardial effusion. There have been no other readmissions for cardiac related morbidity.

DISCUSSION

The case for adopting the E-vita OPEN PLUS™ for treating complex aneurysms and dissections of the thoracic aorta, in a carefully selected group of people, is supported by the evidence.[6] Using the E-vita OPEN PLUS™ has advantages: this approach can simplify the surgical procedure, could remove the need for a second procedure and the associated risk of serious complications, and it should therefore be considered for people: who would otherwise need a two-stage repair procedure because their aortic disease extends into or beyond the distal part of their aortic arch (into the proximal descending aorta), but who would not need additional intervention (such as stent grafting) in the descending aorta.

The largest series published on E-vita is the International E-vita Open Registry (IEOR).[5]

Our results (Table 4) reveal slightly lower average patient age. The times found in our cases was similar to the ones found on literature, or even shorter. Our center adopted the island technique for arch vessel re-implantation, as we think is the best compromise between functional outcome and reduced circulatory arrest time. This technique could justify the shorter circulatory arrest times.

Regarding neuroprotection, in all patients, we provided moderate hypothermia (24ºC) with bilateral anterograde cerebral perfusion and a very careful de--airing. An important part of the procedure, to obtain good outcomes, is anesthetic management, in this respect neuromonitoring is vitally important. In all patients a BIS and an INVOS® monitor were used to access the trend of median oxygen saturation in the brain bilaterally, so we can access the quality of the anterograde selective cerebral perfusion in both sides, in real time. All this measures can help justify the absence of central neurological complications and the good neurologic outcomes, in our series.

None of the patients required more than 72h of ventilatory support.

Only one patient required aminergic support more than 24 hours and only one required red cell transfusion.

The recovery after procedure had fewer complications and the length of stay was less than described in literature.

Table 3 **Data recorded from intra and postoperative periods**

Intraoperative		n patients	%
Aminergic support	Noradrenaline	1	17
	Dobutamine	1	17
Blood Product usage	Red Blood Cell	1	17
	Fresh Frozen Plasma	6	100
	Platelets	5	83
	Cryoprecipitate	0	0
	Fibrinogen	3	50
	Prothrombin Complex Concentrate	1	17
Sinus Rhythm at end of surgery		5	83
Postoperative		**n patients**	**%**
Aminergic support > 24h		1	17
Intubation > 72h		0	0
Renal failure (acute, non-dialysis)		1	17
Re-exploration		0	0
Low output syndrome		0	0
Visceral ischemia		0	0
Stroke		0	0
Spinal cord injury		0	0

Table 4 **Comparison of CHVNG/E experience with International E-vita Open Registry[5]**

Comparative Table	CHVNG/E	IEOR
Age (years)	56	60
Male patients (%)	50	74
CPB time (min)	204	235
Circulatory Arrest Time (min)	63	134
Renal failure (%)	17	26
Stroke (%)	0	6
Re-exploration (%)	17	14
Spinal cord injury (%)	0	8
Prolonged ventilation (%)	0	33
Mortality (total) (%)	0	27
Mortality (hospital) (%)	0	14
Mortality (30 day) (%)	0	12
Length of stay (days)	10	19

In all patients there was a reduction of aneurism sac size and positive aortic remodeling and all where asymptomatic in regard to cardiovascular symptoms.

CONCLUSIONS

The use of E-vita OPEN PLUS™ seems a safe and efficient option for patients with complex aortic arch pathology, providing for a technically easier surgery in comparison to the conventional prosthesis.

In our experience, surgery allowed treatment of multisegmental thoracic aortic disease with satisfactory short- and mid-term results. Despite the short follow-up period, patients are asymptomatic and have evidence of aneurysmal sac involution and positive aortic remodeling.

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