ORIGINAL ARTICLE

OUTCOMES OF DIFFERENT TYPES OF STENT-GRAFT IN ENDOVASCULAR ABDOMINAL AORTIC ANEURYSM REPAIR: LONG-TERM EXPERIENCE OF A HIGH COMPLEXITY COLOMBIAN CENTER, THE FIRST LATIN AMERICAN EXAMPLE

ABSTRACT

Introduction: Endovascular abdominal aortic aneurysm repair (EVAR) devices are associated with a higher rate of complications at 5-year follow-up. At least 30% of patients with EVAR devices require some type of reintervention (whether endovascular or open) at 10-year follow-up. These complications include endoleak, abdominal aortic aneurysms rupture, graft migration, occlusion or infection. The objective of this paper was to determine the rates of failure for each type of EVAR stent-graft used in our local population. Also, this paper is the first step to create a Colombian and Latin American transnational EVAR device registry. **Material and method:** Single-center retrospective observational cohort study. Thirty-four patients with abdominal aortic aneurysms (AAA) treated with EVAR were included from 2011 through 2017. Data were collected from the patients' electronic medical records. **Results:** The stent-graft Endologicx Ba (Endologix, Irvine, CA, United States), Excluder (W.L. Gore, Newark, DE, United States), Zenith (Cook Medical, Bloomington, IN, United States), and Nellix endovascular aneurysm sealing system (EVAS) (Endologix, Santa Rosa, CA, United States) were not associated with any endoleaks or any type of complications after the EVAR procedure. The Aorfix (Lombard, Didcot, United Kingdom), and Endurant (Medtronic, Minneapolis, MN, United States) stent-grafts had rates of type II endoleak (in 1 and 2 patients) of 2.9% and 5.8%, respectively that closed spontaneously. No stent-graft developed type I, III or IV endoleaks or any endovascular or open reinterventions were needed. **Conclusions:** This study shows that the different types of stent-graft used for to treat AAA with EVAR can be used in a safe and feasible way with good postoperative clinical outcomes in the Latin American population.

Keywords: *Abdominal Aortic Aneurysm, Endovascular Procedure, Stents.*

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INTRODUCTION

The endovascular repair (EVAR) of abdominal aortic aneurysm (AAA) has been on the rise since 1991[1] when the feasibility of EVAR was demonstrated by Parodi et al.[2] and Volodos et al.[3]. A total of 80% of the non-ruptured AAA are treated endovascularly in the United States. In Colombia the rate of AAA treated with EVAR has increased since 2007 but we still don't have a national registry with objective data[1-3].

The average cost of a stent-graft for EVAR is $7000 and new stent-grafts for EVAR are developed regularly. Often these new stent-grafts keep the same name for marketing purposes but have a different graft design and structure. These updates regarding EVAR stent-graft are not always available for scrutiny and have limited clinical evidence. In Latin America and more specifically Colombia, the regulatory requirements for the use of stent-grafts vary from one country to the next[1].

The EVAR devices have a higher rate of complications at 5-year follow-up. At least 30% of the patients with EVAR devices at 10-year follow-up require some type of reintervention (whether endovascular or open). These complications include endoleaks, AAA rupture, graft migration, occlusion or infection. Commercially available EVAR systems vary in important ways. The stent-graft material, design, and fixation mechanism vary among different brands, and each device has its own strengths and weaknesses. Back in 2013 and 2015 Duffy et al.[4,5] performed two systematic reviews published in Cochrane that revealed the lack of randomized trials comparing different stent-grafts in the world and Latin America[4,5]. Each stent-graft design could fail differently, but in Latin America and Colombia these results have never been pooled and compared. The objective of this paper was to determine the rates of failure for each type of EVAR stent-graft used in our local population. Also, this paper is the first step to create a Colombian and Latin American transnational EVAR device registry.

METHODS

Study design and setting

Single-center retrospective observational cohort study. The study was conducted in the Hospital Militar Central, Bogota, Colombia. Patients were selected from a database with planned EVAR to treat AAA from 2011 through 2017. Data were collected from the patients' electronic medical records. Hospital Militar Central and Universidad Militar Nueva Granada ethics committees approved the study.

Sample

Patients aged 61 years and over treated with elective EVAR with an average 3-year follow-up were eligible for inclusion. Patients treated with open AAA repair and emergency AAA repair were excluded. Subjects with non-degenerative AAA, thoracic, thoraco-abdominal or isolated iliac aneurysms, and complex aneurysms (fenestrated, extreme anatomy, eg, angled neck, short neck) were excluded too.

EVAR devices

The tent-grafts (and manufacturers) included were Zenith (Cook Medical, Bloomington, IN, United States); Zenith Low Profile (Cook Medical); Endurant (Medtronic, Minneapolis, MN, United States); Excluder (W.L. Gore, Newark, DE, United States); Endologix Ba AFX (Endologix, Irvine, CA, United States); Nellix endovascular aneurysm sealing system (EVAS) (Endologix, Santa Rosa, CA, United States); Anaconda (Vascutek, Inchinnan, Glasgow, United Kingdom); Aorfix (Lombard, Didcot, United Kingdom); Powerlink (LeMaitre, Burlington, MA, United States); Talent (Medtronic); AneuRx (Medtronic); and Incraft (Cordis, Milpitas, CA, United States).

Variables and measurements

Demographic variables

The following demographic data were collected: age and gender.

Clinical baseline variables

The preoperative baseline characteristics collected from the electronic medical records were comorbidities (arterial hypertension, type 2 diabetes mellitus, dyslipidemia, and hypothyroidism), location and size of the AAA.

Surgery-related variables

The following surgery-related variables were collected: type of stent-graft, and manufacturer.

Outcome variables

The primary endpoints of this study were the occurrence of Clavien-Dindo grade 2 and, above all, the postoperative complications.

The secondary endpoints were complications that occurred during or after surgery defined as endoleaks, AAAs rupture, graft migration, occlusion or infection, need for graft explantation and reintervention (endovascular or open).

Data analysis

Continuous variables were expressed as medians with interquartile ranges (IQR). Categorical variables were expressed as numbers and percentages. All analyses were performed using SPSS statistical

software, version 20.0 (SPSS Inc., Chicago, IL, United States). The Chi-square test was used to establish the presence of correlations between the type of aortic stent-graft used and the endoleak.

RESULTS

Fifteen patients were treated with open AAA repair and 70 patients with AAA EVAR from 2011 to 2017. Twenty-five patients had insufficient data in their clinical records. One patient died during the EVAR procedure due to general anesthesia complications. After the application of inclusion and exclusion criteria, 34 patients were included **(Figure 1)**. Their median age group was 71-80 years old (50%). A total of 82.35% of patients were males and 17.65% females. The identified comorbidities were arterial hypertension in 31 patients (91.17%), dyslipidemia in 11 patients (32.35%), type 2 diabetes mellitus in 5 (14.7%), and hypothyroidism in 8 patients (23.52%). A total of 70.5% of the patient had multiple comorbidities. The mean size of the AAA when the EVAR was performed was 60 mm (47.05%) **(Table 1)**.

FIGURE 1. Flowchart of the study recruitment

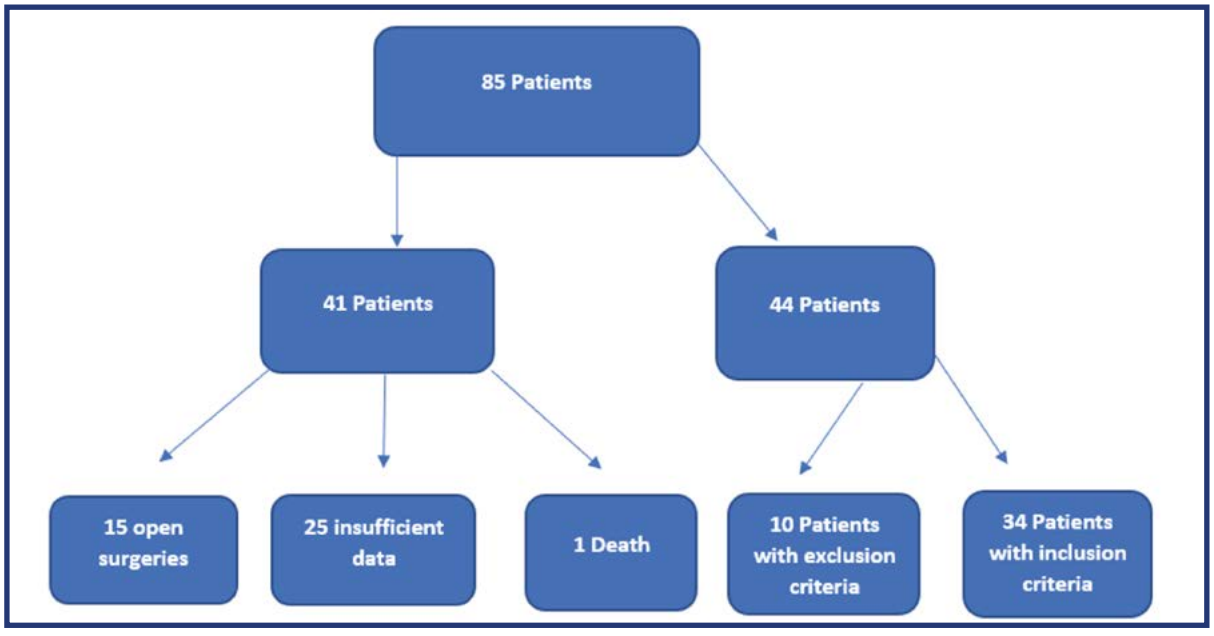

TABLE 1. Patient demographics and clinical characteristics

	N=34	%
Age (years)		
-61-70	7	20,59
-71-80	17	50
-> 80	10	29,41
Gender		
-Male	28	82,35
-Female	6	17,65
Comorbidities		
Arterial hypertension	31	91,17
Dyslipidemia	11	32,35
Type 2 diabetes mellitus	5	14,70
Hypothyroidism	8	23,52
Abdominal aortic aneurysm size (mm)		
45-50	7	20.58
51-55	3	8.82
56-60	8	23.52
> 60	16	47.05

In the 34 patients included in the present study the following types of stent-grafts and manufacturers were used: Zenith (Cook Medical, Bloomington, IN, United States); Endurant (Medtronic, Minneapolis, MN, United States); Excluder (W.L. Gore, Newark, DE, United States); Endologix Ba AFX (Endologix, Irvine, CA, United States); Nellix endovascular aneurysm sealing system (EVAS) (Endologix, Santa Rosa, CA, United States); and Aorfix (Lombard, Didcot, United Kingdom) **(Figure 2)**.

The Zenith Low Profile (Cook Medical); Anaconda (Vascutek, Inchinnan, Glasgow, United Kingdom); Powerlink (LeMaitre, Burlington, MA, United States); Talent (Medtronic); AneuRx (Medtronic) and Incraft (Cordis, Milpitas, CA, United States) stent-grafts and manufacturers were not used.

The stent-graft Endologicx Ba (Endologix, Irvine, CA, United States), Excluder (W.L. Gore, Newark, DE, United States), Zenith (Cook Medical, Bloomington, IN, United States) and Nellix endovascular aneurysm sealing system (EVAS) (Endologix, Santa Rosa, CA, United States) did not present endoleaks or any type of complications after the EVAR procedure. The Aorfix (Lombard, Didcot, United Kingdom) and the Endurant (Medtronic, Minneapolis, MN, United States) stent-graft had rates of type II endoleak (in 1 and 2 patients) of 2.9% and 5.8%, respectively that closed spontaneously and were not statistically significant (P = .712). No stent-graft developed type I, III or IV endoleaks, and endovascular or open reintervention was not required **(Table 2)**.

DISCUSSION

In this study no EVAR stent-graft developed graft-related failures (type, I, III, IV, and V endoleaks) in an median 5-year postoperative follow-up. Only 2 types of EVAR stent-grafts in our study had postoperative complications associated with the stent-graft. The only postoperative complication after AAA EVAR reported in our study was endoleak and the 3 cases were type II endoleaks with a cumulative incidence of 6.7% (Aorfix (Lombard, Didcot, United Kingdom). Also, the Endurant stent-graft (Medtronic, Minneapolis, MN, United States) had a cumulative incidence of 2.9% and 5.8% (in 1 and 2 patients, respectively). Type II endoleaks are the most frequent type found after the AAA EVAR, with rates of 10% to 45% in the medical literature available. A total of 35% to 79.9% of all type II endoleaks resolve spontaneously, which is consistent to our findings. Also, type II endoleaks are patient-related (due to retrograde flows from an arterial branch excluded by the stent-graft like the inferior mesenteric, lumbar, intercostal, and accessory renal arteries), and not stent-graft-related per se. Also, type II endoleaks are less clinically relevant compared to the other types, and more variably detected and operated on[1,6,7,8].

The Registry of Endovascular Treatment of Abdominal Aortic Aneurysm and the European Collaborators on Stent-graft Techniques for Abdominal Aortic Aneurysm Repair Registry confirmed the safety and efficacy profiles of endovascular repair with a reported 30-day

FIGURE 2. EVAR devices used

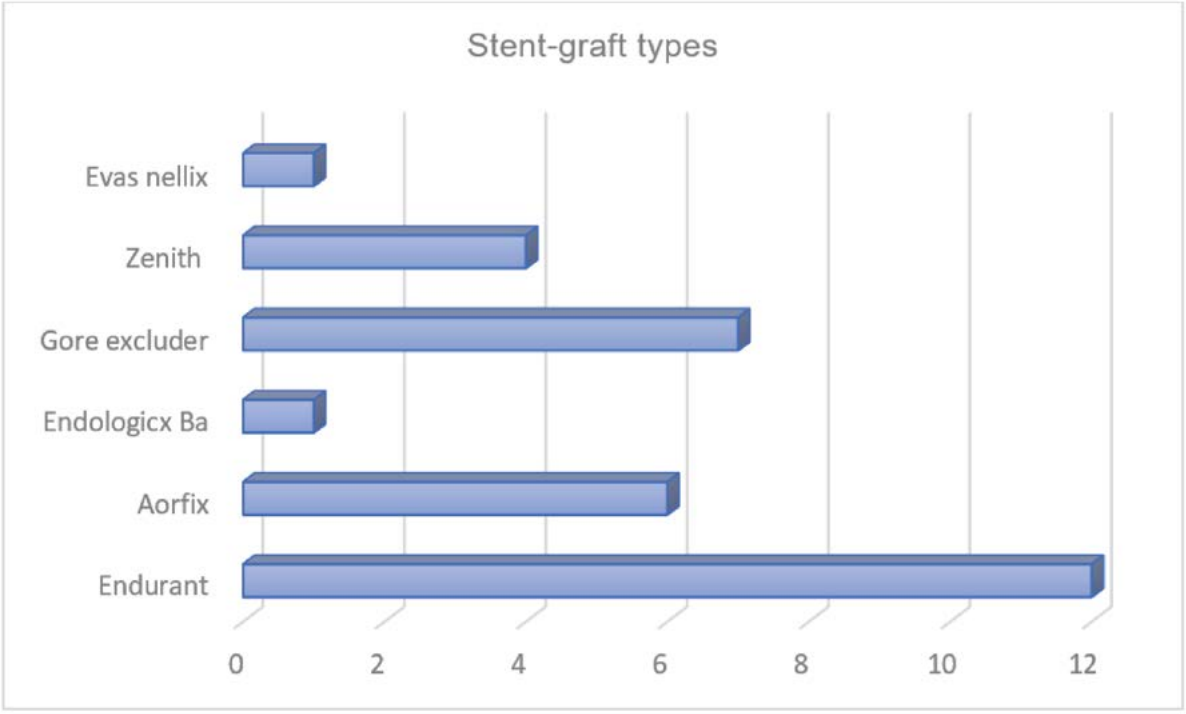

TABLE 2. Frequency of outcomes according to the different stent-grafts used

STENT-GRAFT TYPES	N = 34	ENDOLEAK TYPE	ENDOLEAK PERCENTAGE	REINTERVENTION	RUPTURE	P (CHI-SQUARE TEST)
Aorfix	6	II	(1) 2,9%	-	-	0,712
Endologicx Ba	1	-	-	-	-	-
Gore Excluder	9	-	-	-	-	-
Zenith	5	-	-	-	-	-
Endurant	12	II	(2) 5,8%	-	-	0,712
Evas Nellix	1	-	-	-	-	-
Total	**34**	**-**	**3**	**0**	**0**	**-**

procedural mortality rate of 2.9% and 3.1%, respectively. The 3 largest randomized clinical trials (RCT) that assessed the differences between EVAR and open surgery are the EVAR I, the DREAM, and the OVER. These RCT included patients with AAA > 5.5 cm that were eligible for open surgery, and also for EVAR that were randomly assigned to open repair or EVAR. The results of these studies concluded that EVAR is associated with a significantly lower 30-day mortality rate (EVAR I, 1.6% vs. 4.6%; DREAM, 1.2% vs. 4.6%; and OVER, 0.5% vs. 3.0%), and shorter intensive care unit (ICU) and hospital stays. Nevertheless, the survival advantage is lost at 2-year follow-up. This evidence is similar to the 30-day procedural mortality rate showed in our study of 1.42% (1 patient)[9-14].

A total of 10% of patients can require reintervention due to type I endoleaks seen on the 30-day imaging monitorization. Type I endoleaks occur at either the proximal (Ia) or distal (Ib) attachment sites and can be seen during the insertion of the initial stent-graft. Type III endoleaks are often due to 3 mechanisms: a defect within the graft material, a structural failure causing the separation or the components or due to inadequate overlapping. Type I and type III endoleaks indicate direct communication with the systemic blood flow, the aneurysmal sac and require immediate repair. The initial approach to repair type I endoleaks involves angioplasty of the damaged attachment site. The second-line option includes a bare-metal stent (large stent sizes with strong radial force) that can be placed over the attachment site. The third treatment strategy consists of inserting an overlapping stent-graft in the nonadherent portion of the stent-graft. The last endovascular treatment option is the deployment of a new stent-graft component across the defect or junctional separation followed by further angioplasty to remold the structural components of the stent-graft. However, type I endoleaks that occur at the proximal docking site can be more technically challenging because they originate distally to the takeoff of the renal arteries, and open repair can be required. Type IV endoleaks are due to the patients full anticoagulation with heparin perioperatively and are self-limited resolving as the patient's coagulation returns to normality. Type V endoleaks are classified as an enlarging aneurysmal sac without a visible endoleak generating endotension in the aneurysmal sac that can require EVAR reintervention or conversion to open repair. In this study no stent-graft developed type I, III, IV or V endoleaks or endovascular or open reintervention were needed[14,15].

Back in 2018, Kent et al.[1] conducted a systematic review and meta-regression to evaluate the safety of device registries for AAA EVAR. A total of 147 moderate quality papers involving 27 058 patients were included. Multiple outcomes were pooled. The estimated rate of overall endoleak (excluding type II) at 2 years was 5.7% +/- 0.6% compared to our series (0%). The pooled rate of reintervention was 11.1% +/- 0.7% at 2 years compared to our 0% rate of reintervention[1]. In our study there were no differences in pooled endoleak rates (excluding type II endoleaks) among different stent-grafts. In this study, expert consensus defined non-inferiority as better performance compared the worst performing stent-grafts (25%). The main outcome in the expert consensus was the cumulative rate of endoleaks (excluding type II) to evaluate the stent-graft safety profile. An ideal device registry should recruit, at least, 525 patients to demonstrate non-inferiority in the rate of endoleaks reported (excluding type II) while 492 patients are required to demonstrate non-inferiority in the stent-graft reintervention rate. Only 2 out of the 147 studies included in this systematic review achieved this minimum standard[1]. In our study, we found that 491 patients didn't show acceptable non-inferiority at 2 years for new or altered EVAR stent-graft. Almost all previous publications have captured lower patient numbers. With performance varying among the different devices, and with new devices being introduced regularly, there is an urgent need to capture higher quality long-term data on EVAR stent-grafts. In our study there was no

correlations between the aortic stent-graft type and the endoleaks ($P = .712$).

In the studies reviewed by Kent et al.[1] attrition rates were particularly high with a 29% pooled attrition rate at 1 year. In our study, the attrition rate was 35.7% (25 patients). The EVAR arms of RCTs, and even the EVAR 2 trial only had a maximum of 21% attrition rate at 1 year. The best way to avoid attrition is to improve poor follow-up in future registries. The other problem is that attrition will mask higher stent-graft failure rates compared to those found at 1 year[1]. The follow-up protocols in patients treated with AAA EVAR are vital to reduce complications. Also, it allows early detection and endovascular or open treatment of late postoperative complications. The better understanding of the clinical characteristics, stent-graft types, and the long-term progression of patients after AAA EVAR will facilitate that we can choose the best approach for this highly complex condition with unique features to reach the best possible outcomes[15].

Adherence to the manufacturer indications for use (IFU) produces better clinical results. In this study all stent-grafts were used according to the IFU. However, in the real clinical scenario's only 30% to 70% of all stent-grafts are actually inserted following the IFU anatomy. This gives more objectivity to our results[1,4,11,15].

Stent-grafts evolve continuously over the time to reduce their complications and improve their outcomes. However, length of follow-up remains a critical issue. Kent et al.[1] shows only a median follow-up from their 147 included studies of 24-month duration[1]. The creation and development of national and global registries is urgently required for EVAR stent-grafts including anatomical considerations to determine which is the ideal stent-graft design, configuration, and material for AAA EVAR procedures[16]. This study could be the beginning of this in our country and Latin America.

Study limitations

The findings of this study should be interpreted within the context of its design. It's a single center non-randomized study with a small sample. Results should, therefore, be viewed as hypothesis-generating to be able to conduct future studies. All data were retrospectively collected from the patients' electronic medical records and outcomes are based on what was registered. It was no possible to subdivide stent-graft by updates under these because the generation of updated stent-graft had very few data available. The strengths of this study are the detailed short and long-term clinical outcomes of AAA EVAR devices, the patients' follow up, and the adherence to the manufacturer IFU regarding the use of stent-grafts.

CONCLUSIONS

This study shows that the different stent-graft types used for AAA EVAR can be used in a safe and feasible way with good postoperative clinical outcomes in our population. Nevertheless, we must develop a national and Latin American Device Safety Registry for AAA EVAR to reach the minimum of patients required for a registry to show acceptable non-inferiority at 2 years for new or altered EVAR stent-grafts reported in the medica literature available. This is the first step for the creation of the Colombian/Latin American Device Safety Registry for AAA EVAR that will allow us to obtain statistical significative data to choose the best stent-graft options from the surgical market.

Conflicts of interest

The authors have no disclosures to declare.

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