Original Article

An early single-center experience with the Relay double inner-branch arch endograft

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Background: Open surgery remains the gold standard technique for the treatment of aortic arch pathologies, although endovascular techniques offer a new opportunity for patients deemed unfit for open repair. This paper assesses the early outcomes of patients treated with a double inner-branched arch endograft in a single, tertiary-care institution.

Methods: All consecutive cases of elective endovascular arch repair from 2016 to 2022 were included in a prospective database. All procedures were performed using the custom-made Relay® (Terumo Aortic—Bolton Medical Inc., Sunrise, FL, USA) double inner-branched endograft; an extra-anatomical bypass was associated in all cases to preserve the patency of supra-aortic trunks. Comorbidities, periprocedural data, immediate results and follow-up complications were analyzed.

Results: Twelve patients were treated during the study period [mean age 74±7 years, 100% male, 58% American Society of Anesthesiologists (ASA) risk ≥3]. Treated conditions included aneurysms (n=9), one pseudoaneurysm, one aortic ulcer and a type IA endoleak. The technical success rate was 100%. Early complications included respiratory insufficiency (n=3; 25%), stroke (n=1; 8.3%), acute coronary syndrome needing coronary stenting (n=1; 8.3%), and one perioperative death (n=1; 8.3%) secondary to an intracranial bleeding after coronary stenting. One patient required early reintervention due to retroperitoneal iliac access bleeding (n=1; 8.3%). During a median follow-up of 15.5 (range, 0–44) months, four patients suffered neurological events (two of them of cardioembolic origin), one reintervention was needed (subclavian anastomosis pseudoaneurysm), and a type IB endoleak was diagnosed. Overall mortality was of 17% (n=2), with an 83% overall survival at 2 years. The aortic-related death-free survival was 100%.

Conclusions: Endovascular treatment of aortic arch pathology is feasible and shows promising early mortality and stroke rates in high-risk candidates. The main short and midterm goal should be minimizing neurological complications. A longer follow-up is mandatory to determine the effectiveness of the technique and to detect device related complications.

Keywords: Aortic arch; endovascular repair; hybrid repair; aortic aneurysm; inner branch device

Submitted Aug 03, 2023. Accepted for publication Nov 03, 2023. Published online Dec 26, 2023.
doi: 10.21037/jtd-23-1211
View this article at: https://dx.doi.org/10.21037/jtd-23-1211

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Introduction

Background

Open repair provides excellent outcomes for the treatment of aortic arch pathologies in high-volume reference centers, showing 30-day mortality and stroke figures ranging from 5–15% and from 4–12%, respectively. Accordingly, it is still considered the gold standard (1). These results come from improvements in anesthesia and critical care, advances in surgical technique (moderate hypothermic circulatory arrest, antegrade cerebral perfusion, frozen elephant trunk...), and a careful patient selection. Around 20–40% of patients are rejected for an open procedure, and half of them die due to rupture (2). For this reason, various endovascular options have emerged that may represent a treatment opportunity for these patients. However, all these techniques pose major challenges (anatomical selection criteria, high hemodynamic stress, precision of deployment) for vascular and cardiac surgeons.

Rationale and knowledge gap

The high rate of endoleaks have limited parallel endografting to emergencies or as a rescue procedure (2), and debranching arch techniques continue to be an invasive intervention suffering from inconveniencies for open and endovascular procedures without a significant improvement of mortality and stroke rates (3). Subsequently, the future of endovascular arch repair points towards specifically dedicated endografts with scallops, fenestrations or branches. Aortic branches are more tolerant regarding planning, design and implantation, although they require sealing in zone 0 and their main disadvantages continue to be anatomical requirements: roughly a half of the candidates are non-suitable for any double or triple branch endograft (4). Accordingly, case series have limited sample sizes. Meanwhile, stroke represents a major concern, and the long-term durability of this technique must be cleared up in the following years.

Highlight box

Key findings

- 100% of technical success for of elective endovascular arch repair, and 8.1% early stroke-death rate.

What is known and what is new?

- Open surgery remains the gold standard technique. Endovascular treatment is a feasible option for patients who are not good candidates for open repair.
- A new patient cases series, all performed in the same institution, using the custom-made Relay® endograft.

What is the implication, and what should change now?

- It is a feasible technique but neurological complications should be reduced.

Objective

The objective of this study is to describe the early experience using the Relay® Branch endograft (Terumo Aortic-Bolton Medical Inc., Sunrise, FL, USA) for aortic arch repair in patients considered unfit for open surgery, in a single institution. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1211/rc).

Methods

All patients undergoing elective aortic arch endovascular repair with the custom-made RelayBranch endograft (Terumo Aortic—Bolton Medical Inc., Sunrise, FL, USA) during the 2016–2022 period were included in a prospectively-maintained database. This endograft was designed with a large cannulation window in the outer curvature and two antegrade parallel inner branches, usually for the brachiocephalic trunk (BCT) and the left common carotid artery (LCCA). A triple branch configuration with a retrograde inner tunnel for the left subclavian artery (LSA) is also available. The custom-made Relay® Branch endograft is shown in *Figures 1-4*. The Institutional Review Board waived the need for ethics approval and specific informed consent for this study given its retrospective nature and the anonymized treatment of data. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Case selection and procedure

Patients presenting with aortic arch aneurysm, pseudoaneurysm, penetrating ulcer or proximal type 1A endoleak [after a previous thoracic endovascular aortic repair (TEVAR)] were considered candidates for this technique. All patients were discussed in a multidisciplinary medical board, with participation of anesthesiologists, vascular and cardiac surgeons. Endografts were specifically planned according to each patient's arch anatomy, using the preoperative computed tomography angiography (CTA)

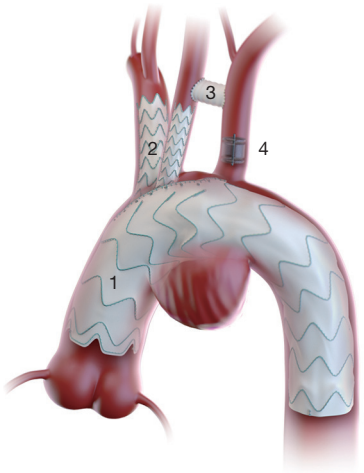

Figure 1 Schematic representation of the Relay® custom-made double inner-branch endograft after complete deployment and LCCA-LSA bypass. 1: main body. 2: supraaortic endograft extensions, for BCT and LCCA. 3: left carotid to left subclavian bypass. 4: occlusion of the LSA with a plug device. LCCA, left common carotid artery; LSA, left subclavian artery; BCT, brachiocephalic trunk. Image courtesy of Terumo Aortic.

and the OsiriX (Pixmeo, Geneva, Switzerland) or the Endosize (Therenva, Rennes, France) workstations.

A Dacron graft bypass was performed under general anesthesia, through a single supra-clavicular or with separated supra and infra-clavicular incisions, from the LCCA to the LSA or left axillary artery (LAA) in order to preserve the left vertebral and LSA patency. A vascular plug occlusion device (Cera™ Plug, Lifetech Scientific Co. Ltd., Shenzen, China), with at least 20% oversizing, was then inserted through the LSA and released proximally to the vertebral artery ostium. Cerebrospinal fluid (CSF) drainage was not considered in any of the cases. Endograft implantation was performed in a hybrid operating theatre (Artis Zeego, Siemens Healthcare GmbH, Erlangen, Germany), under rapid pacing provided with a temporary pacemaker through right jugular access. The retrograde implantation of the bridging stents for BCT and LCCA was sequentially performed through an open exposure and cross-clamping of both common carotid arteries to provide embolism protection. Excluder® iliac limbs (W. L. Gore and Associates, Inc., Flagstaff, AZ, USA) were used as bridging stents in most cases.

Follow-up and definitions

The standard surveillance protocol included a three-phase postoperative CTA at one and six months postprocedure, and yearly thereafter in the absence of endoleaks or complications. Analyzed variables included demographics, baseline characteristics and comorbidities, aortic measurements, procedural details, complications, reinterventions, and mortality over time. Minor complications were defined as arterial access pseudoaneurysms, wound infection or hematoma and nerve palsy. Major complications were recorded following the endovascular reporting standards for systemic complications (4,5). Major adverse events (MAEs) were defined as the occurrence of any of the following: ischemic heart attack, cerebrovascular accident (permanent or transitory), respiratory insuffiency (need of high oxygen flow ventilation or mechanical invasive ventilation), renal impairment (increase by >0.5 mg/dL of basal creatinine levels), poly-transfusion (>3 blood cell units), spinal cord ischemia, emergent re-intervention or 30-day mortality. The presence of endoleaks and aneurysm growth were also registered.

Statistics

Continuous variables were described using mean and standard deviation (SD) or median and interquartile range, and categorical variables were described using frequencies. Due to the small sample size, associations were not considered for testing. Kaplan-Meier survival estimations were built for freedom of complications and overall survival. All calculations were performed using the software SPSS version 24.0 (IBM Corp., Armonk, NY, USA).

Results

Twelve consecutive patients, all male with a mean age of 74±7 years were included. Baseline characteristics and most frequent comorbidities were: hypertension (92%), history of tobacco abuse (83%), dyslipidemia (75%), renal insufficiency (33%) and chronic obstructive pulmonary disease (COPD) (25%). 58% of the patients had an American Society of Anesthesiologists (ASA) risk equal or greater than three. Other conditions are summarized in *Table 1*. The most common indication for treatment was aortic arch aneurysm (nine cases, 75%), follow by one

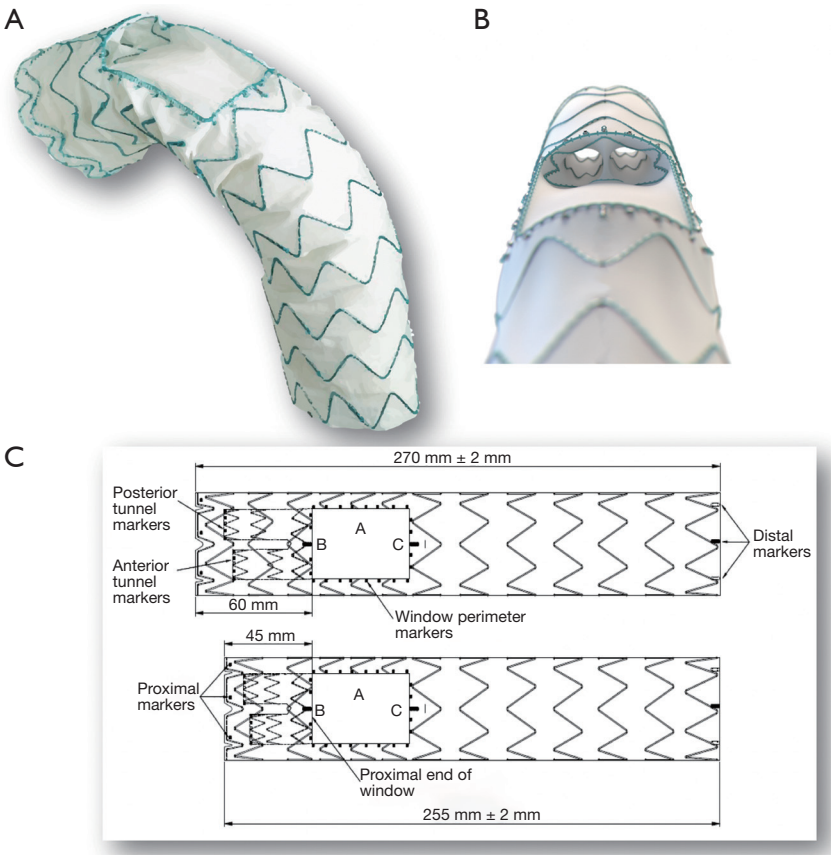

Figure 2 Relay(r) Branch endograft (Terumo Aortic-Bolton Medical Inc., Sunrise, FL, USA). (A) Lateral presentation showing the window and tunnels for the inner branches. (B) Detail of both tunnels for the inner branches. (C) Radiopaque marker scheme. All images courtesy of Terumo Aortic.

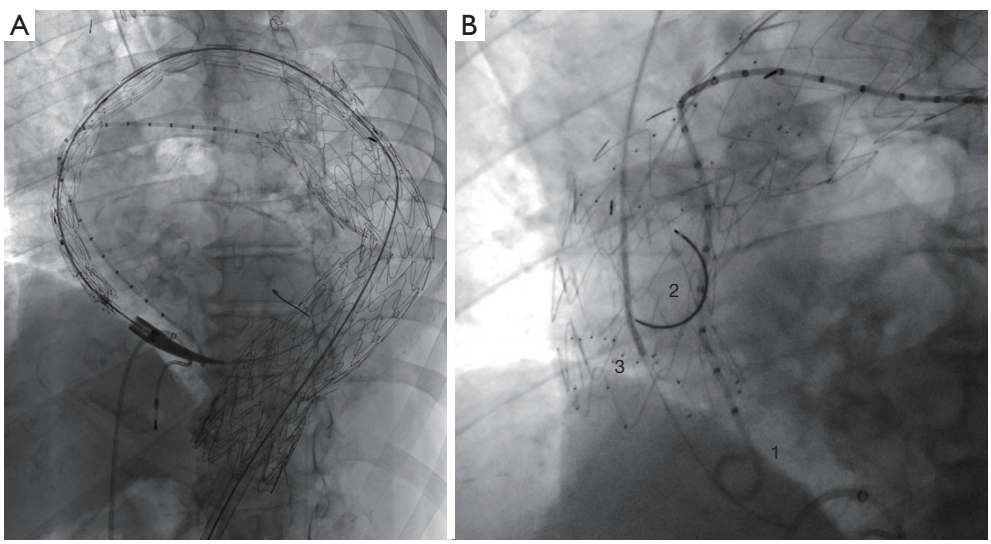

Figure 3 Intraoperative images. (A) Patient with a previous TEVAR. Detail of device in ascending aorta previous to its deployment. (B) 1: fluoroscopic catheter on ascending aorta, femoral approach. 2: extra stiff wire on ascending aorta by femoral approach. 3: hydrophilic catheter and hydrophilic wire in ascending aorta once first tunnel (brachiocephalic trunk) has been catheterized. TEVAR, thoracic aortic endovascular repair.

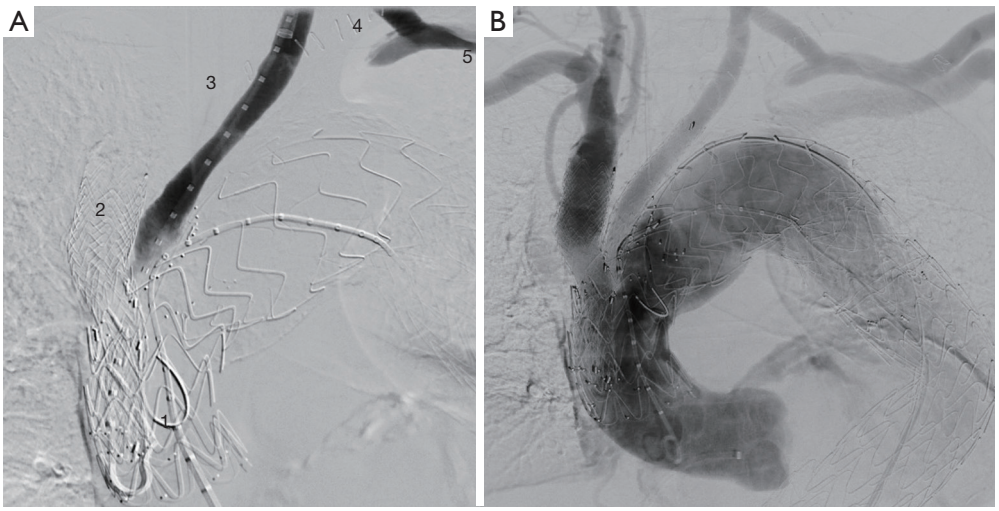

Figure 4 Intraoperative image. (A) 1: main body. 2: brachiocephalic branch extension. 3: left common carotid artery with angiographic catheter through the tunnel, arteriography was made through left carotid introducer sheath. 4: left carotid to left subclavian artery bypass. 5: left subclavian artery. (B) Final angiography.

aortic arch pseudoaneurysm, one penetrating ulcer and one type IA endoleak after a previous TEVAR surgery (*Table 1*). Overall, the mean aortic diameter considering all indications was 62±13 mm (67±10 mm for the nine aneurysmatic patients).

Technical success rate was 100%. Six patients (50%) developed a transient phrenic nerve palsy related to the LCCA-LSA bypass, with full recovery during the follow-up period; no incisional wound complications were registered. 50% of the patients needed blood transfusion. Major perioperative complications included: respiratory insufficiency in 3 patients (25%). One acute myocardial infarction (AMI) (8%) occurred 72 hours after the index procedure in a patient who had had an uneventful postoperative recovery. He needed urgent coronary stenting with fibrinolysis, full anticoagulation and an aggressive antiplatelet protocol, that lead to a post-intervention major stroke due to intracranial bleeding (8%). Mild renal impairment was noticed in another case (8%) and one more patient needed reintervention to achieve hemostasis (after a retroperitoneal exposure to get an adequate iliac access). Respiratory and renal failures were successfully solved with medical treatment. There was one death (8%) within the first 30 postoperative days, in the same patient who suffered the AMI and fatal hemorrhagic stroke, so an 8% combined 30-day mortality-stroke rate is considered. The median in-hospital stay was 9 days (range, 5–67 days). *Table 2* summarizes all complications.

Median follow-up was of 15.5 months (range, 0–44 months). During this time period, four strokes occurred (42%): two of them were secondary to a cardioembolic source, of which one led to the patient's death. A cardioembolic etiology was defined by either a neurologist or a neurosurgeon. Both patients suffered from atrial fibrillation under anticoagulation therapy. Considering the total number of patients with neurological events (42%), two died, two had complete recovery, and one was left with severe functional limitations.

A type IB endoleak (8%) was detected in a patient with severe comorbidities, who rejected correction. Aneurysm growth was noticed in one patient, managed with surveillance due to poor medical conditions. No aneurysm rupture occurred. One reintervention was needed to repair a LCCA-LSA bypass anastomotic pseudoaneurysm (in the subclavian anastomosis).

As an incidental finding, a thin layer of thrombus (1 mm of thickness) was noticed inside the brachiocephalic branch in one of our patients without clinical repercussion. Follow-up complications are summarized in *Table 3*. Median time until the first follow-up complication was 359 days (range, 12–1,408 days) (*Figure 5*). The mortality rate at the end of the follow-up period was 17% (n=2), with an 83% overall death-free survival at 2 years. The aorta-related death-free survival was 100%.

Table 1 Comorbidities and baseline characteristics

Variables	Values
Tobacco abuse history	10 [83]
Hypertension	11 [92]
Diabetes mellitus	2 [17]
Dyslipidemia	9 [75]
Coronary artery disease	2 [17]
Coronary revascularization	2 [17]
Atrial fibrillation	3 [25]
Renal impairment	4 [33]
COPD	3 [25]
Previous stroke	1 [8]
Peripheral arteriopathy	1 [8]
ASA risk score	
2	5 [42]
3	5 [42]
4	2 [17]
Aortic arch pathology	
Aortic arch aneurysm	9 [75]
Aortic pseudoaneurysm	1 [8]
Aortic arch penetrating ulcer	1 [8]
Proximal type 1A endoleak	1 [8]
Mean aortic diameter (mm), (n=12)	62±13

Data are presented as n [%] or mean ± standard deviation. COPD, chronic obstructive pulmonary disease; ASA, American Society of Anesthesiology.

Table 2 Early postoperative outcomes (first 30 days)

Variables	Values
Transient phrenic nerve palsy	6 (50.0)
Blood transfusion	6 (50.0)
Intraoperative blood transfusion (>3 units)	0
Respiratory dysfunction	3 (25.0)
Acute myocardial infarction	1 (8.3)
Major stroke	1 (8.3)
Acute renal insufficiency	1 (8.3)
Need for dialysis	0
Spinal cord ischemia	0
Graft thrombosis	0
MAE	4 (33.3)
Re-intervention	1 (8.3)
Death	1 (8.3)
Operation time (hours)	7.3 [6.1–8]
Length of hospital stay (days)	9 [5–67]

Data are presented as n (%) or median [interquartile range]. MAE, major adverse event.

Table 3 Complications over follow-up

Variables	N (%)
Stroke	4 (33.3)
Re-intervention	1 (8.3)
Endoleak (type Ib)	1 (8.3)
Overall end-of-follow-up mortality	2 (16.7)

Discussion

Endovascular treatment of the aortic arch is a highly-demanding procedure due to the anatomical complexity of this region, hemodynamical stress and pulsatility. Technical improvements of specifically-designed devices allow offering this treatment to patients otherwise rejected for surgery. In our series of 12 cases with the RelayBranch endograft, we were able to achieve promising results in early mortality and stroke rates, at the cost of considerable complication rates.

Previously published studies have shown similar results to ours. An Italian registry with the Relay® Branch arch device showed an in-hospital mortality of 16.7% and a stroke rate of 12.5% (6). Also, The Italian Registry with the Najuta® endograft (Kawasumi Labortories, Inc., Tokyo, Japan) describes an early mortality of 1.3% and a 3.9% stroke rate (7). However, a high proportion of patients were anatomically unsuitable for this device (mainly due to outer curvature pathology). Similarly, a study by Tsilimparis *et al.* reported promising results using a Zenith® (Cook Medical, Bloomington, IN, USA) preloaded fenestrated thoracic endograft, with early mortality and stroke figures of 3.7% and 7.5% respectively (8). Besides, Canaud *et al.* published the results with physician-modified endografts (PMEGs), using a Valiant Captivia® thoracic device (Medtronic Inc., Santa Rosa, CA, USA) with a preloaded guidewire for the LSA. A 2% mortality and 4% stroke rate was noticed, with a reintervention rate of 11% (9). This approach remains

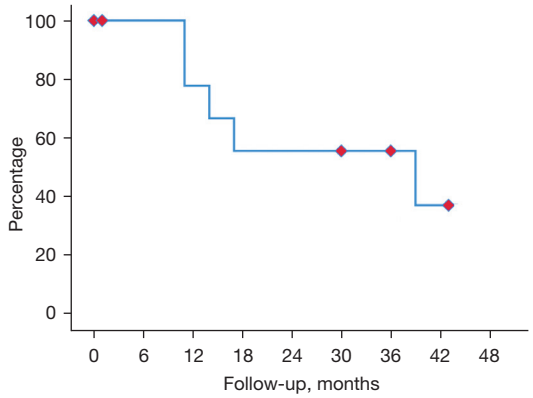

Figure 5 Freedom of major complications over follow-up. X-axis: follow-up (months). Y-axis: estimated percentage of patients without major complication over time.

an option in emergent cases, but entails pushing the limits of the device. Finally, a report with the Nexus™ endograft (Artivion, Inc., Kennesaw, GA, USA) in 28 patients showed a 7.1% 30-day mortality and a 3.6% stroke rate (10). This device has a single branch, and needs an extensive cervical extra-anatomic debranching, increasing the risk of surgical and systemic complications.

The suitability of the device for endovascular aortic arch repair may be conditioned by the degree of atherosclerotic affectation, tortuosity and angulation. Besides, the quality of the proximal sealing zone in the ascending aorta, an available sealing length in supra-aortic vessels and their diameters remain the most important issues to consider. Anatomical suitability criteria are quite similar for both inner-branch platforms, with the Relay® allowing treatment of ascending aortic diameters up to 42 mm, compared to the Zenith® going up to 38 mm. Stroke is the most feared complication for both devices. The largest experience in the literature comes from the Zenith® endograft, showing early mortality rates ranging from 0% to 13.2%, stroke rates from 3% to 15%, and early reinterventions in a 15% of the cases (11,12). For the same device, Tsilimparis *et al.* published their experience in 54 patients, achieving technical success rates of 98% and a 30-day mortality and major stroke incidence of 5.5% respectively (13). For the Terumo Aortic devices, mortality and stroke rates have been reported between 0–16.7% and 4–25%, respectively, needing early redo-interventions in up to 16.7% of patients (14). In 2018, Czerny *et al.* published their experience using the double branch platform in 15 patients from four centers, with in-hospital mortality and stroke rates of 6.7% and 13.3% (15).

Performing double inner branch endovascular repair is a technically complex procedure. The impact of the learning curve on the outcomes was already assessed by Haulon *et al.* in 2014, reporting early mortality and transient ischemic attack (TIA)/stroke rates of 30% each, in the first 10 patients compared to 7% and 10.7%, respectively, in the subsequent group of 28 patients (11). Our early experience with the Relay® Branch endograft shows a 100% technical success, with an acceptable combined early mortality-stroke rate of 8%. These figures are consistent with previously reported experiences from other centers, and the early postoperative complication rates are also within the reported margins. Our results can be, at least partially, explained by an adequate selection of the candidates and an affordable complexity of the procedure using the Relay® Branch device.

An important issue to take into account is the need of the LSA revascularization, in order to minimize the risk of stroke, spinal cord and upper limb ischemia. A phrenic nerve palsy has been described in up to 25% of the patients after a LCCA-LSA bypass (16). In our series this complication was noticed in a half of the patients and, even though all of them had a complete recovery, it could have contributed to raise the respiratory complication rate. For that reason, and after this paper analysis, we have changed our surgical strategy. Nowadays we perform a left carotid to LAA bypass, avoiding the need of phrenic nerve mobilization and lowering the palsy rates. The Relay® triple branch design, with minimal manipulation of the supra-aortic trunks, would be the best option to avoid this complication and probably is the next step, with recent reports communicating encouraging results (17-19).

Ischemic stroke represents the Achiles' heel of this technique. During our follow-up period (median 15.5 months) one reintervention was needed to repair a distal anastomosis LCC-LSA pseudoaneurysm; the patient suffered a postoperative stroke, with a final result of death. In addition, four other strokes were registered during follow-up. In an attempt to minimize these risks, embolic protection devices have been employed with contradictory results (14). Benefits of flushing the delivery system with carbon dioxide have also been mentioned; Kölbel *et al.* reported just one minor stroke in a 36-patient series with the Zenith® platform (20). The advantages of this maneuver with the Relay® device are unclear, since its dual sheath system allows to initiate the first delivery steps in the descending aorta, below supra-aortic vessels takeoff. Main considerations to reduce the stroke incidence, apart from an

adequate case indication and meticulous technique, would be to choose the appropriate branch device and the optimal medical treatment. Postoperative care is also an important key point in the prevention of neurological complications.

Long-term results of inner branch arch endografts are still awaited. Kudo *et al.* reported six aortic events after a mean follow-up of 4.0 years. The aortic event-free survival rates at 1 and 5 years were 85.7% and 81.6%, respectively and the aorta-related death-free rate was 95.8% at 5 years (14). More studies with long follow-up are still lacking.

Limitations

This report has several limitations that should be taken into account. Mainly, it is a retrospective analysis from a prospectively maintained database, with a small sample size that prevents inferential statistics to be performed. Accordingly, potential mortality and stroke predictors could not be identified. The heterogeneity of pathologies (25% non-aneurysmal) could act as confounding factor for the results. However, a single institution experience is reported, while most of the largest published series are multicenter studies where this weakness may be even greater. Besides, the median follow-up in our series was 15.5 months, highlighting the need of long-term analyses.

Conclusions

Endovascular treatment of the aortic arch using the Relay® Branch endograft is a complex procedure with promising early mortality and stroke rates in high surgical risk candidates. The main short and mid-term goal should be to minimize neurological complications. A longer follow-up is mandatory to determine the effectiveness of the technique and to detect device-related complications.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1211/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1211/dss

Peer Review File: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1211/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1211/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The Institutional Review Board waived the need for ethics approval and specific informed consent for this study given its retrospective nature and the anonymized treatment of data. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

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Cite this article as: Iglesias Iglesias C, González Canga C, Abril Ramiro F, Alonso Pastor A, Álvarez Marcos F, Alonso Pérez M. An early single-center experience with the Relay double inner-branch arch endograft. J Thorac Dis 2023;15(12):6721-6729. doi: 10.21037/jtd-23-1211

