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Total Endovascular Repair of the Aortic Arch: Initial Experience in the Netherlands

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Background. **We report procedural and early results in the Netherlands of the Relay Branch device (Terumo Aortic, Sunrise, FL) for total endovascular repair of the aortic arch.**

Methods. **Between 2014 and 2018, all consecutive patients who received the Aortic Relay double-branched stent graft in the Netherlands were included in a multicenter, retrospective registry.**

Results. **The Relay Branch device was used in 11 patients to treat saccular (n = 4), fusiform (n = 5), or false aneurysms (n = 2) in the aortic arch. Patients were deemed unfit or extreme high-risk for open (redo) surgery. The brachiocephalic trunk and left common carotid artery were branched using a retrograde approach in all cases. Additional surgical left subclavian artery revascularization was performed in 8 patients. The main device and the branches were successfully introduced, positioned, and deployed with complete exclusion of the aortic pathology in all patients (100% technical success). There was no retrograde type A dissection or conversion to open surgery. Two procedure-related deaths occurred, both caused by perioperative or postoperative strokes. There were 2 minor strokes with full recovery. One patient recovered from transient paraplegia after spinal fluid drainage. No permanent paraplegia was observed. Follow-up imaging showed persistent adequate exclusion of aortic arch pathology. Mean follow-up was 17 months (range, 3-42 months).**

Conclusions. **Total endovascular aortic arch repair using the Relay Branch device is technically feasible and effective in excluding aortic arch pathology. The observed stroke rate in the initial experience, however, was considerable. Although appealing, this new less-invasive technique should be carefully introduced and its progress thoroughly evaluated.**

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Surgical repair of aortic pathology with involvement of the aortic arch remains a challenge, partly due to its location, with difficult handling of the distal region through a median sternotomy, but mostly due to the need for temporary systemic circulatory arrest. Core and cerebral cooling as well as selective brain perfusion are required and have associated risks. Nonetheless, following a strict protocol for heart, brain, and systemic protection, aortic arch surgery represents an acceptable risk.[1] However, because of all the necessary invasive adjunctive procedures, open surgery may not be the best treatment option for all patients. Older, comorbid patients may benefit from a less-invasive approach that allows for quicker recovery. As a result, hybrid procedures have gained popularity. The frozen elephant trunk technique enables proximalization of the distal anastomosis and extends the treatment more distally using a stent graft.[2,3]

Also, aortic arch (partial) debranching, followed by endovascular repair, does not require a heart-lung machine and has been widely used.[4,5] The invasiveness of the procedure along with stroke risk continues to be concerning, however. Increasing experience in stent grafting the thoracic and thoracoabdominal aorta has led to a growing interest in the endovascular treatment of the aortic arch. Its distal part (when involved in descending thoracic aortic pathology) has already been successfully treated by endovascular means using the chimney technique, scallops, selective debranching of the left subclavian artery (LSA), and single-branched stent grafts that are currently being studied.[6-10]

The double-branched Relay Branch device (Terumo Aortic, Sunrise, FL), including a main stent graft for the aortic arch containing 2 inner branches that enable retrograde extension into the brachiocephalic trunk (BCT) and left common carotid artery (LCCA), offers a total endovascular approach. In this study we report the perioperative and early postoperative results from all patients treated with this device to date in the Netherlands.

Patients and Methods

The Institutional Review Board and Medical Research Ethics Committees United in Utrecht (reference number W17.118) waived the need for informed consent.

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Patients

Between 2014 and 2018, 11 consecutive patients were treated with the Relay Branch device for aortic arch pathology in 3 medical centers in the Netherlands and were included in this registry. All of the patients were discussed in a multidisciplinary setting consisting of a cardiothoracic surgeon, vascular surgeon, and interventional radiologist. When deemed unfit or at high-risk for open surgery, the total endovascular approach was considered and evaluated by the physicians and the stent graft company (Terumo Aortic).

Requirements for the proximal landing zone in the ascending aorta (zone 0) are a diameter between 30 and 40 mm (to enable the necessary oversizing) and a length of at least 65 mm between the sinotubular junction and the BCT measured over the outer curvature. In addition, the BCT and LCCA diameters should be at least 7 mm and not exceed 20 mm (Figure 1). The main stent graft was generally oversized in diameter by approximately 10% to 15%. Finally, the optimal angulations of the C arm were determined for an orthogonal projection of the aortic arch and both the BCT and LCCA to position the branches.

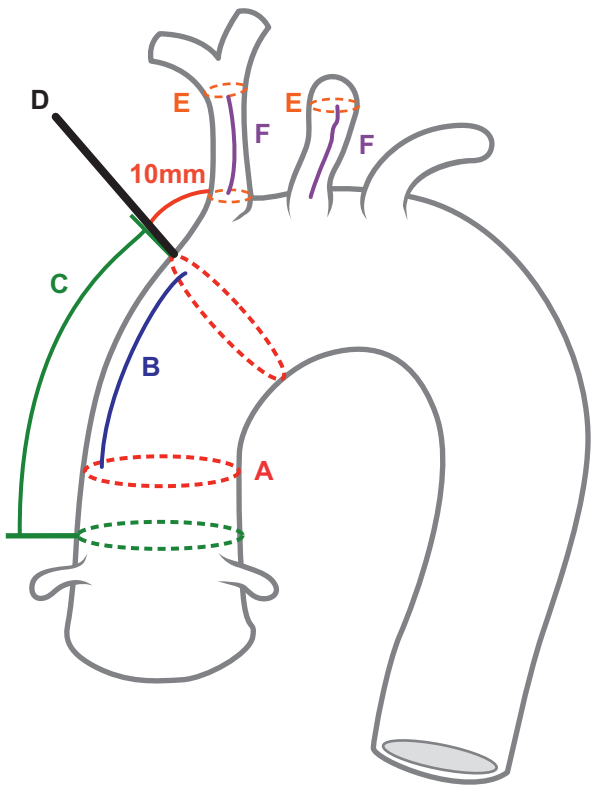

Figure 1. Measurements for the double-branched device. A, Diameter of the ascending landing zone, maximum of 40 mm. B, Length of the ascending landing zone, minimum of 30 mm. C, Length of the sinotubular junction to the brachiocephalic trunk (BCT) measured on the outer curvature of the aorta, minimum of 65 mm. D, Zero point, 10 mm from the BCT measured on the outer curvature of the aorta; beginning of the fenestration. E, BCT and left common carotid artery (LCCA) diameter, between 7 and 20 mm. F, Length of BCT and LCCA, at least 25 mm. (Image courtesy of Terumo Aortic, Sunrise, FL.)

Prosthesis

The endoprosthesis used in all our patients was designed by Terumo Aortic as the Relay Branch device. The main device is a customized version of the standard Relay NBS Plus stent graft, which holds a Communauté Européenne (CE) mark, composed of a series of self-expanding nitinol springs stacked in tubular configuration and sutured on a low-porosity vascular polyester stent graft. The proximal end of the stent graft is always a covered stent graft.

The main device has a fenestration on the cranial part of the stent graft giving access to the internal tunnels for the branches that need to be extended into the BCT and LCCA. The branches are customized versions of the iliac limbs used with the Treo (Bolton Medical, Sunrise, FL) abdominal endovascular stent graft system. Owing to the self-alignment mechanism of the precurved nitinol inner catheter and the 2-sheath delivery system, the 50-mm-long (its width depending on the diameter) fenestration with the internal tunnels tends to automatically align with the outer curve of the aorta. The easily recognized and distinguishable multiple radiopaque markers help to align the fenestration and distinguish the internal tunnels. The delivery system of the main device is 25F for the outer diameter (correlating to 8.4 mm), and the delivery system of the branches is 14F (correlating to 4.7 mm; Figure 2).

Procedure

The procedure was performed under general anesthesia in a hybrid operating theater. The LSA was surgically revascularized by a surgical bypass or transposition (depending on cerebrovascular anatomy and surgeon preference) and could be plugged to prevent backflow to the aortic arch if deemed necessary. A surgical cutdown or total percutaneous approach (n = 1) of the femoral artery was performed, through which a curved stiff guidewire was placed in the left ventricle, crossing the aortic valve under transesophageal echocardiographic (TEE) guidance. Unfractionated heparin was administered intravenously to obtain an activated clotting time (ACT) of at least 200 seconds and the ACT was regularly checked. The outer sheath of the delivery system was introduced and positioned at roughly the distal landing zone in the proximal descending thoracic aorta.

Next, the flexible inner sheath containing the main device was carefully advanced to the ascending aorta. In all cases, the nose cone crossed the aortic valve, again under transesophageal echocardiographic guidance. The radiopaque markers indicating the beginning of the fenestration were placed at the "zero point" (Figure 1), located 10 mm proximal of the BCT. The device was gradually deployed by retracting the inner sheath using rapid ventricular pacing to temporarily cease cardiac output. The introducer sheath was retracted to allow undisturbed flow to the leg. The branches were then placed through the left and right common carotid arteries through a separate supraclavicular incision on each side.

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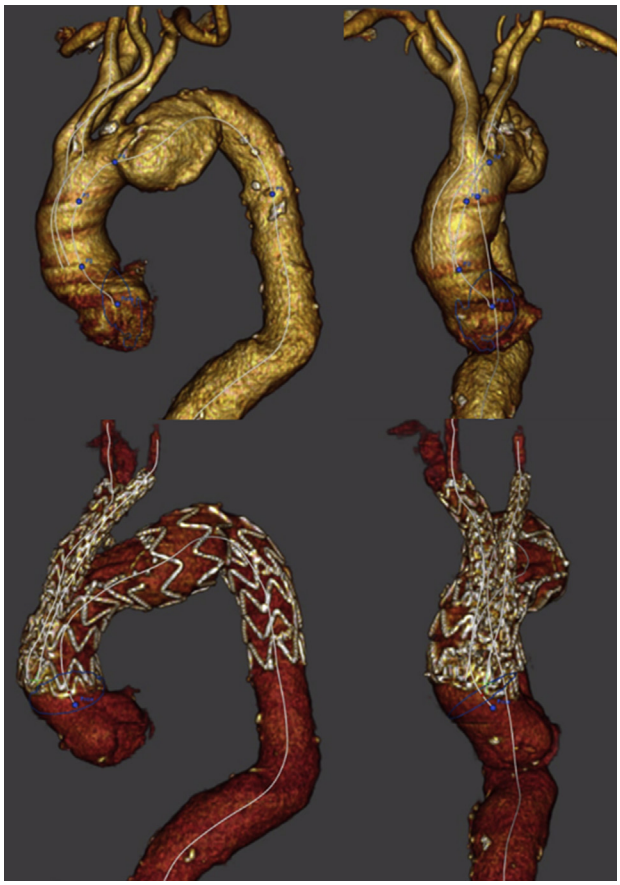

Figure 2. Three-dimensional reconstructions of imaging from a 78-year-old patient with an aneurysm in the arch. The top row shows the aorta before the procedure. The bottom row shows the placement of a Relay Branch stent graft (Terumo Aortic, Sunrise, FL) with branches in the brachiocephalic trunk and left common carotid artery.

To prevent stroke, the carotids were clamped or temporarily closed using a vessel loop, allowing an extensive flush before reopening.

Radiopaque markers distinguish the 2 internal tunnels: the posterior tunnel for the extension to the BCT and the slightly shorter anterior tunnel for extension to the LCCA. To ensure the position of the guidewire in the inner tunnel, a test ballooning was performed before the branches were placed in the tunnels. The entire procedure was performed using transcranial Doppler or near-infrared spectroscopy monitoring. Finally, a completion angiography was made.

In case of type 1a endoleaks, ballooning under rapid ventricular pacing is advised before the branches are placed because the inner branches will re-expand to their original size. When a type 1a endoleak is observed after the placement of the branches, a balloon should also be placed simultaneously in both branches to prevent the branches from collapsing. To prevent thrombosis in the branches, 3 months of coumarins or dual antiplatelets are advised next to lifelong use of aspirin. A control CT was performed after 3 months, 1 year, and annually thereafter.

Statistical Analyses

For the statistical analyses, descriptive analyses are reported. Continuous variables are reported with the standard mean/median and interquartile range (IQR). Categorical data are represented by number and percentage.

Results

A total of 11 patients received a double-branched stent graft to treat an aortic arch saccular (n = 4), fusiform (n = 5), or false aneurysms (n = 2). The aneurysms were a median diameter of 6.4 cm (IQR, 5.2-9.6 cm). Five patients had isolated aortic arch aneurysms, and the aneurysm in the remaining 6 originated in the descending aorta and extended into the distal aortic arch. All patients were deemed unfit (n = 5) or too high risk (n = 6) for open (redo) repair. Patient-specific baseline characteristics are described in Table 1.

Perioperative Results

In all patients, the main device and the branches were successfully introduced, positioned, and deployed with complete exclusion of the aortic pathology (ie, no endoleak), resulting in a technical success rate of 100%. Eight patients received concomitant surgical LSA revascularization by LSA-LCCA bypass (n = 5) or by axilloaxillary bypass (n = 3). No retrograde type A dissections, unintentional coverage of side branches (including the coronaries), or conversions to open repair occurred.

Perioperative or postoperative strokes resulted in 2 procedurally related deaths. Both patients were treated for fusiform distal aortic arch aneurysms; 1 was deemed unfit and the other high-risk for open repair. One patient (with a history of transient ischemic attacks) received an additional axilloaxillary bypass for persistent LSA flow. In the other patient, the intended the LSA bypass was not performed due to severe adhesions deep in the neck. Introduction, positioning, and deployment of the main device as well as both branches was all straightforward, and in the second patient, no malperfusion or emboli were observed intraoperatively on transcranial Doppler. Both patients, however, showed clinical signs of severe stroke postoperatively, and CT scans of the brain confirmed extensive diffuse infarction of the cerebrum with poor prognosis.

Postoperative Neurologic Results

Two minor strokes occurred immediately after the procedure. One patient had a saccular aneurysm in the aortic arch that was treated with the double-branched stent graft and concomitant LSA bypass graft and suffered postoperative motor disorders (right foot and hand). The other patient was also treated for a saccular aneurysm of the proximal descending aorta (double-branched stent graft with an axilloaxillary bypass) and experienced right-side hemiparesis. Both patients fully recovered after being initially discharged to a rehabilitation facility.

Table 1. Baseline Characteristics

Patient	Sex	Age (y)	COPD	HT	Previous CVA/ TIA	DM	PAD	Creatinine Levels (μmol/L)	Previous Aortic Surgery	Other	Type of aortic pathology	Unfit/high risk for open repair
1	Male	81	Yes	Yes	Yes	No	No	148	No	No relevant	Fusiformic aneurysm	Unfit
2	Female	74	No	Yes	Yes	No	No	54	No	Diminished left ventricle function	Fusiformic aneurysm	High risk
3	Male	72	Yes	Yes	No	Yes	Yes	80	Twice bifurcation prosthesis	No relevant	Saccular aneurysm	Unfit
4	Female	75	No	Yes	Yes	No	Yes	54	Bifurcation prosthesis and TEVAR descending aorta with LSA bypass	Lung carcinoma	Pseudoaneurysm	Unfit
5	Male	82	No	No	No	No	No	86	Bifurcation prosthesis	Prostatectomy to treat carcinoma	Fusiformic aneurysm	Unfit
6	Male	66	No	Yes	No	No	No	66	Repair of popliteal aneurysm	Squamous cell carcinoma of the esophagus	Saccular aneurysm	Unfit
7	Male	73	Yes	Yes	No	No	No	349	Open AAA repair with Dacron[a] graft	No relevant	Fusiformic aneurysm	High risk
8	Male	69	No	Yes	Yes	No	No	145	Supracoronary ascending aortic replacement	No relevant	Saccular aneurysm	High risk
9	Male	78	No	No	No	No	No	102	Bifurcation prosthesis	No relevant	Fusiformic aneurysm	High risk
10	Male	73	Yes	Yes	No	No	No	105	Bifurcation prosthesis	Prostatectomy to treat carcinoma	Saccular aneurysm	High risk
11	Male	69	No	Yes	No	No	No	79	Supracoronary ascending aortic replacement	No relevant	Postdissection aneurysm	High risk

[a]DuPont, Wilmington, DE.

AAA, abdominal aortic aneurysm; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; DM, diabetes mellitus; HT, hypertension; LSA, left subclavian artery; PAD, peripheral artery disease; TEVAR, thoracic endovascular aortic repair; TIA, transient ischemic attack.

No permanent paraplegia was observed in our small cohort of patients; however, 1 patient did experience temporary paraplegia. This instantly and fully recovered after the drainage of spinal fluid with a cerebral spinal fluid catheter and medically induced hypertension. No additional distal stent grafts were placed in this patient other than the main double-branched stent graft for the aortic arch (length, 27 0 mm) as well as LSA revascularization by an LSA-LCCA bypass. In 3 patients, concomitant additional distal stent grafts were placed as planned to fully exclude the long segment of aortic pathology. No signs of paraplegia were seen in any of these patients.

Other Postoperative Results

No type 1 endoleaks were seen on the control CT scans made before discharge, all aortic pathology was adequately excluded, and all branches were patent without stenosis. In 1 of the 2 patients who sustained a fatal stroke, the postoperative CT scan of the brain also included the thoracic aorta, which showed complete exclusion of the aortic arch pathology (ie, no endoleak).

The median duration of the procedure (often including surgical revascularization of the LSA) was 300 minutes (IQR, 240-360 minutes), and median duration of radiation was 50 minutes (IQR, 42.5-52.5 minutes). No complications caused by the longer fluoroscopy time were seen. Temporary renal function disorders occurred in only 1 patient (doubled preoperative creatinine value), which normalized to preoperative values without special treatment. The median hospital stay was 13 days (IQR, 6-50 days), with a median of 5 days (IQR, 1-14 days) spent in the intensive care unit. The 7 patients without neurologic problems were discharged home.

Follow-up

Mean follow-up was 17 months (IQR, 3-42 months), with no loss to follow-up. Two patients required a reintervention, 1 to treat a type 2 endoleak originating from the LSA and 1 patient with left arm claudication. In the first patient, the endovascular plug placed during the initial procedure did not fully cover the LSA, so additional coils were subsequently placed; this was an uneventful procedure. The second patient experienced symptoms of left arm claudication for which an axilloaxillary bypass was performed (no surgical revascularization of the LSA was performed during the placement of the double-branched stent graft). Besides the previously mentioned type 2 endoleak originating from the LSA, no other endoleaks or stent graft migrations were seen on follow-up CT scans. The LCCA branch in 1 patient showed a circular in-stent stenosis in the distal part of the stent graft after 30 months. Because this was an asymptomatic stenosis, a conservative strategy was followed. A CT scan 42 months after the procedure showed total occlusion, but the patient continued to be asymptomatic, and conservative treatment (the patient was already being treated with coumarins because of atrial fibrillation) continued.

Comment

With this national cohort of 11 patients we have shown that the Relay Branch device is a feasible and effective technique in excluding several types of aortic arch aneurysms. The perioperative technical success was 100%, and all aortic pathologies were excluded, with no type 1a endoleaks or late strokes during follow-up. However, the observed stroke rate in this early experience was considerable: 2 were fatal and 2 were minor with full recovery.

The gold standard for treating aortic arch pathology today is open surgery, even though hybrid procedures are gaining in popularity as a way to minimize these operations for frail patients. In all of these procedures, the stroke rate remains an issue of concern. Open repair through a median sternotomy with total arch repair and use of a (frozen) elephant trunk has a reported stroke rate of 3% to 10%.[1,2,4,11,12] However, the pathology treated in these reports consisted mostly of ascending aneurysms continuing into the aortic arch.

The patients in our cohort had isolated aortic arch aneurysms or proximal descending aortic aneurysms involving the distal arch, which makes comparison difficult. Open repair of the distal aortic arch and proximal descending aorta pathology with an interposition graft through a lateral thoracotomy may be more comparable, but these more extensive repairs can be performed in often lower-risk patients. Alternatively, hybrid procedures with a debranching of the supraaortic vessels, followed by the placement of a stent graft in the aortic arch, has shown promising results. Unfortunately, this technique has similar stroke rates of 3% to 10%.[4,11,12] However, the patients in our cohort were considered unfit or too high risk for open repair, including debranching techniques. In addition to this generally higher risk, 4 patients had a known cerebral ischemic event in their medical history, which is a known risk factor for recurrent ischemic events.[13] The 2 patients who sustained a fatal stroke had a large aortic arch aneurysm with intraluminal thrombus, increasing the perioperative stroke risk.[14] These patients would also have had an increased stroke risk when treated with open or hybrid procedures.

Studies of 2 cohorts in which an endovascular device with 2 inner branches was used to treat aortic arch pathology in high-risk patients have been published.[15,16] The cohort in one study comprised 15 patients who were treated using the same device used in our cohort. Disabling stroke was noted in 6.7% and nondisabling stroke in 13.3%, with a median follow-up of 263 days. Note that the 5 patients from the Netherlands were also included (with shorter follow-up) in this cohort.[15] The other cohort consisted of 38 patients who were treated with a custom-made branched stent graft by Cook Medical (Bloomington, IN). A technical success rate of 84.2% was achieved, with a reported stroke rate of 15.8% during a median follow-up of 12 months.[16] A separate analysis of the first 10 patients compared with the latter 28 patients treated showed a higher rate of intraoperative

complications and secondary procedures in the first group, indicating a learning curve in the technique and the patient selection. Our cohort comprised all patients treated with the device in 3 medical centers, so a similar reduction of complications may be expected in a future cohort (learning curve and patient selection).

A parallel may be seen in transcatheter aortic valve implantation, which initially was only used in patients deemed unfit for open aortic valve repair, but nowadays has substantially improved results in patients at lower surgical risk. Before adoption for this procedure, strict patient selection (firstly unfit or high-risk patients for surgery), suitable anatomical criteria, and stroke prevention measures (such as temporary carotid artery occlusion, filter placement, carbon dioxide flushing of the delivery system) are required. The European Association for Cardio-thoracic Surgery/European Society for Vascular Surgery consensus document recommends endovascular aortic arch repair in zone 0 only in patients unfit for open surgery and with a suitable anatomy and only in centers with an adequate volume of and expertise in both open and endovascular arch repair.[17]

The technique has proven technically successful but still requires a surgical cutdown to place the main device (25F) and the branches (14F). In most patients, a concomitant surgical revascularization of the LSA was performed (making this procedure arguably still hybrid). With lower-profile devices becoming available, a percutaneous approach and a truly total endovascular procedure are possibilities.[18] In our early results, all but branches but 1 were patent, and no type 1 endoleaks were seen on the follow-up imaging. A perioperative control may be helpful to confirm inner branch patency and undisturbed flow to the arch vessels. In addition, in the event of a proximal endoleak, balloon dilatation (with rapid pacing) of the proximal part of the stent graft (containing the inner branches) is possible. Both inner branches will reexpand to their original size. The complexity of the procedure is depicted in a median surgical duration of 300 minutes and a median radiation duration of 50 minutes. However, these extending surgical times and contrast administration did not result in an increase of renal failure.

In conclusion, endovascular aortic arch repair using the Relay Branch device is technically feasible and effective in excluding aortic arch pathology. The stroke rate, however, was considerable. Although appealing, this new, less-invasive technique should be carefully introduced and its progress thoroughly evaluated.

The University Medical Center Utrecht has a consultancy agreement with Terumo Aortic. The authors received no financial aid from a commercial source. The tested technology was purchased from the manufacturer, and the authors confirm that they had freedom of investigation and full control of the design of the study, methods used, outcome variables and results, analysis of data, and production of the written report.

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