Early and midterm results of thoracic endovascular aortic repair using a branched endograft for aortic arch pathologies: A retrospective single-center study

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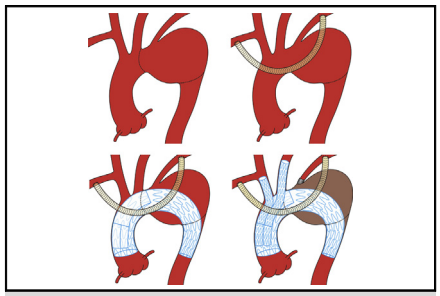
ABSTRACT

Background: Zone 0 landing hybrid thoracic endovascular aortic repair (TEVAR) includes a few moderately invasive surgical procedures. To reduce invasiveness, TEVAR with a branched aortic arch stent-graft can be considered. This study aimed to elucidate the effectiveness of performing TEVAR using a Bolton (Bolton Medical, Inc, Sunrise, Fla) branched endograft by analyzing early and midterm results.

Methods: We enrolled 28 patients (mean age, 78.4 years) who underwent TEVAR with the Bolton branched endograft in Osaka University Hospital between October 2012 and June 2018 with a mean follow-up period of 4.0 years. Double-side and single-side branched devices were used in 24 (85.7%) and 4 (14.3%) patients, respectively.

Results: All procedures were successful; no cases of endoleak or conversion to open repair were noted during the 30-day postoperative period. The perioperative stroke rate was 14.3% (4 out of 28); midterm stroke was not detected. All patients with perioperative stroke had atheroma grade ≥2 in the brachiocephalic artery. No type 1a endoleak was reported during the early or midterm results. The cumulative survival rate, aorta-related death-free rate, and aortic event-free survival rate at 5 years were 80.8%, 95.8%, and 81.6%, respectively.

Conclusions: We achieved satisfactory early and midterm results by using a Bolton branched endograft for high-risk patients with arch pathologies except for high postoperative stroke. Although this treatment method is associated with postoperative stroke, performing strict evaluation of atheroma may prevent such complication. By preventing intraoperative stroke, TEVAR with this custom-made Bolton branched endograft may be considered a less-invasive treatment. (JTCVS Techniques 2020;4:17-25)



Schematic of thoracic endovascular repair using the Bolton branched endograft.

CENTRAL MESSAGE

Early and midterm results of thoracic endovascular aortic repair using a Bolton branched endograft show that preoperative strict atheroma evaluation is important for preventing postoperative stroke.

PERSPECTIVE

When using a custom-made Bolton branched endograft, it is essential to prevent perioperative stroke. The development of perioperative stroke may be prevented by performing a strict preoperative evaluation of atheroma. By preventing perioperative stroke, thoracic endovascular aortic repair using a custom-made Bolton branched endograft may become a less-invasive treatment.

See Commentary on page 26.

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Abbreviations and Acronyms

3D = 3-dimensional
AxA = axillary artery
BCA = brachiocephalic artery
CCA = common carotid artery
LZ = landing zone
MDCT = multidetector computed tomography
TEVAR = thoracic endovascular aortic repair

Video clip is available online.

Aortic arch pathologies are extremely difficult to treat because they require conventional open surgeries, which are highly invasive and complex procedures.[1-3] Recently, hybrid thoracic endovascular aortic repair (TEVAR) gained increasing attention for the treatment of aortic arch pathologies. Hybrid TEVAR is preferred, especially in high-risk patients. However, aortocervical bypasses have to be created during zone 0 landing hybrid TEVAR, which include some moderately invasive surgical procedures.[1,4,5] To reduce the invasiveness, we performed TEVAR using a branched stent-graft, in which complex aortocervical bypass or graft replacement is not required. Therefore, this study aims to elucidate the effectiveness of performing TEVAR using a Bolton branched endograft (Bolton Medical, Inc, Sunrise, Fla).

PATIENTS AND METHODS

Ethics Statement

All protocols of the procedures in this study were approved by the Medical Ethics Committee of Osaka University School of Medicine (No. 15087). After fully explaining the surgical procedures and risks and presenting the results of the multidisciplinary team discussion to the patient, we obtained informed consent from the patient to undergo this procedure.

Patients

From October 2012 to June 2018, 368 patients underwent aortic repair for the treatment of aortic arch pathologies at Osaka University Hospital. Twenty-eight patients who were characterized as high risk for median sternotomy and aortocervical bypasses by several cardiovascular surgeons and cardiologists underwent TEVAR using a Bolton branched endograft.

Preoperative Measurements

All patients underwent contrast-enhanced multidetector computed tomography (MDCT) with 3-dimensional (3D) reconstruction by using an image-processing workstation (Aquarius Intuition, TeraRecon, Durham, NC) preoperatively to evaluate the adequacy of the proximal and distal landing zones (LZ); aortic arch, including the cervical arteries; and access route. MDCT images were acquired with a $\leq$1 mm slice thickness. We routinely followed-up with MDCT a week before discharge, at 6 months postoperatively, and yearly thereafter. The data were reviewed by cardiovascular surgeons who were blinded to this study.

Device and Treatment Strategy

An overview of the Bolton branched endograft is shown in Figure 1. The custom-made branched endograft is fundamentally similar to the Relay NBS graft (Bolton Medical, Inc). This device has a large gate (Figure 1, *A*) to cannulate the cervical devices, with 1 or 2 internal inner tunnels (Figure 1, *B*). For cervical arteries, we used the Bolton cervical stent (Bolton Medical, Inc), the Gore Excluder contralateral leg (WL Gore & Associates, Inc, Newark, Del), and the AAA iliac leg (Cook Zenith; Cook, Inc, Bloomington, Ind) (Figure 1, *C*). To prevent intraoperative stroke, we used the following filter devices: the Parachute (Tri-Med Corp, Osaka, Japan) and the Filtrap (Nipro Corp, Osaka, Japan).

We ensured the following preprocedural conditions regarding the treatment strategy: proximal LZ diameter $\leq$42 mm, proximal LZ length $\geq$30 mm, the length from the proximal LZ to the left common carotid artery (CCA) $\geq$95 mm, and the proximal LZ and the cervical arteries of atheroma grade was 1 or 2.

Surgical Procedure

The procedural steps are shown in Figure 1, *D,* and Video 1. Under general anesthesia, the patients received an extra-anatomical bypass from the right axillary artery (AxA) to the left AxA or from the right AxA to the left CCA and the left AxA using a ringed 8-mm expanded polytetrafluoroethylene graft (Figure 1, *E*). The balloon catheter was then inflated at the orifice of the left subclavian artery to protect against emboli after the bypass.

A pacemaker catheter was inserted for rapid pacing. The rapid pacing (heart rate >160 bpm) was undergone while deploying the main branched graft. A straight wire was used to cross the aortic valve and advanced to the left ventricle. This was then exchanged for a curved superstiff wire. Dyna-CT was performed for 3D mapping. The main device was inserted through the femoral artery approach after inserting a pigtail catheter into the ascending aorta. After delivering the device to the descending aorta, the flexible inner sheath was advanced to the aortic arch and then toward the ascending aorta. We confirmed the precise match between the orifices of the cervical arteries and the device gate by performing standard angiography and 3D mapping. Rapid pacing was started, and the main body of the device was deployed at a constant speed (Figure 1, *F*).

Next, the wire was advanced to the posterior tunnel from the right CCA, and the measurement catheter was advanced to this tunnel to select the cervical device. The stent-graft for the brachiocephalic artery (BCA) was inserted into the tunnel and deployed carefully followed by touch-up ballooning. Stent-graft deployment in the left CCA was performed using the same procedure for the double-side branched stent-graft (Figure 1, *G*). Lastly, we performed coiling of the left subclavian artery using the balloon catheter, which was inserted before deploying the stent-grafts. Aortography was conducted to check for endoleaks and bypass patency.

Follow-up

Follow-up included regular clinical visits at least once every 3 months for the first postoperative year and then once every 6 months or at 1 year thereafter in our hospital. We recorded the confirmed death of the patients through telephone interviews with their families.

The data of aortic events, including known/suspected events, such as stroke, aneurysm enlargement $\geq$5 mm in diameter, or any cases of endoleak, stent-graft migration, aortic rupture, aortic dissection, and prosthetic infection were recorded. Aorta-related death was defined as death due to adverse events secondary to aortic pathologies.

Statistical Analyses

Results are expressed as mean $\pm$ standard deviation and median (interquartile range [IQR]) according to the normality of the distribution, as

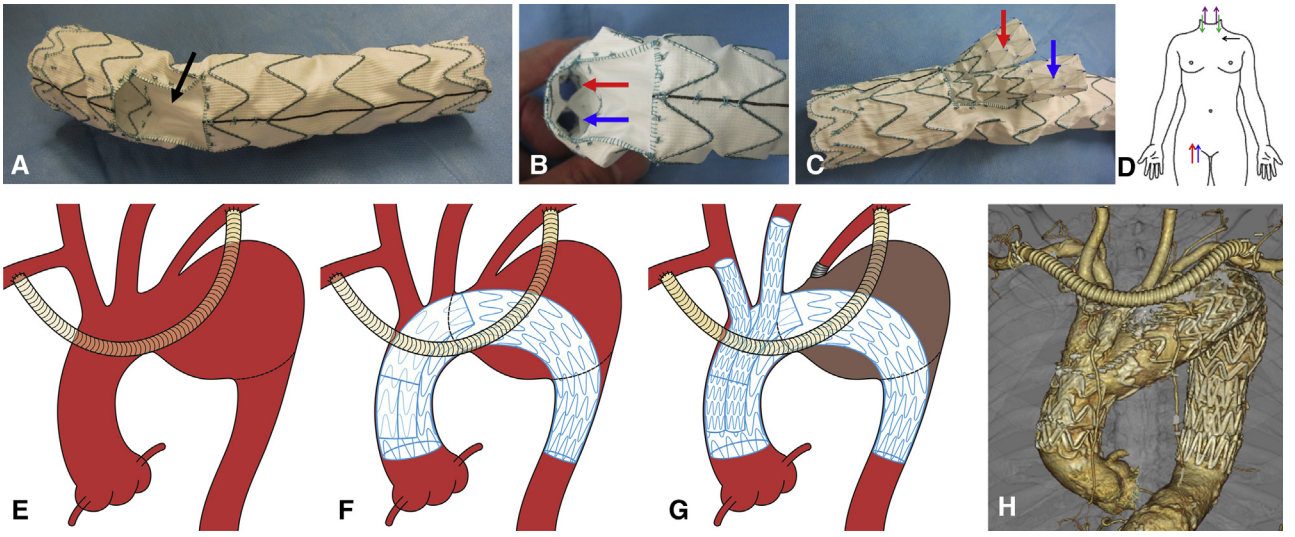


FIGURE 1. Overview of the Bolton branched endograft (Bolton Medical, Inc, Sunrise, Fla) and schema of the surgical procedure of the Bolton branched endograft. A, Main body of the Bolton branched endograft with a large gate (*black arrow*). B, Inner tunnels (brachiocephalic artery [BCA]: *red arrow*, left common carotid artery [CCA]: *blue arrow*). C, Overview of the Bolton branched endograft (BCA: *red arrow*, left CCA: *blue arrow*). D, Overview of the approach site: Bolton branched endograft from the common femoral artery (*red arrow*), pacemaker catheter from the right common femoral vein (*blue arrow*), cervical devices from the CCAs (*green arrow*), filter devices for protecting against emboli from the CCA (*purple arrow*), and balloon catheter for protecting against emboli from the left axillary artery (AxA) (*black arrow*). E, Extra-anatomical bypass from the right AxA to the left CCA using a ringed 8-mm expanded polytetrafluoroethylene graft. F, The Bolton branched endograft is deployed under rapid pacing (heart rate >160 bpm) after confirming the precise match between the orifices of the cervical arteries and the device gate by standard angiography and 3-dimensional (3D) mapping. G, The stent grafts for the cervical arteries are inserted in the tunnels and deployed. H, 3D computed tomography image after the procedure.

assessed with the Shapiro-Wilk test. Categorical variables are presented as counts and percentages. The curves for overall survival and freedom from aorta-related death and aortic events were estimated using the Kaplan-Meier product-limiting method. All statistical analyses were performed using JMP statistical software, version 14.0.0 for MacOS X (SAS Institute Inc, Cary, NC).

RESULTS

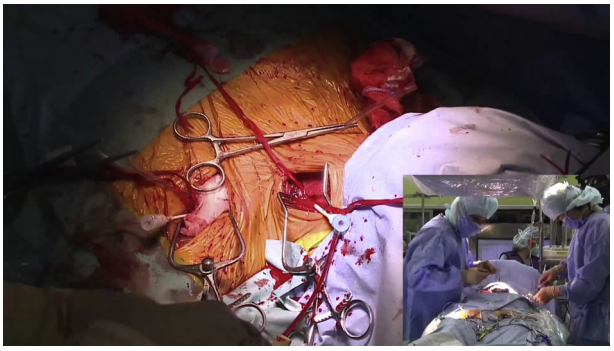
Patient Characteristics

The patient characteristics are listed in Table 1. The follow-up period was 4.0 ± 2.0 years (IQR, 0.5-7.0 years), and all 28 (100%) patients completed the study. The age of the whole cohort was 78.4 ± 6.9 years (IQR, 66-87 years), 15 (53.6%) patients were older than age 80 years, and 17 (60.7%) patients were men. All patients underwent the elective procedure. The pathologies consisted of degenerative aneurysm in 22 (78.6%) patients and dissecting aortic aneurysm in 6 (21.4%) patients. Of 28 patients, 14 (50.0%) had a history of previous cardiovascular surgery. Five (17.9%) patients had previous median sternotomy, and 7 (25.0%) had undergone endovascular aortic repair (TEVAR or endovascular aortic repair). The median logistic European System for Cardiac Operative Risk Evaluation and European System for Cardiac Operative Risk Evaluation 2 were 38.8% (IQR, 33.1%-46.0%) and 6.6% (IQR, 5.7%-8.9%), respectively.

Preoperative measurements using MDCT are summarized in Table 1. The median maximum aneurysm diameter was 56.5 mm (IQR, 54.3-60.8 mm). The mean diameter of the proximal and distal LZ, and the mean length of the lesser proximal LZ were 34.3 ± 3.6 mm, 29.1 ± 3.4 mm, and 34.6 ± 8.5 mm, respectively. Atheroma grade ≥2 was detected in the ascending aorta (9 out of 28 [32.1%]), BCA (6 out of 28 [21.4%]), and left CCA (4 out of 28 [14.3%]).

Procedure Outcomes

The postoperative data are listed in Table 2. All procedures were successful; no endoleaks occurred, conversion to open repair during the 30 postoperative days did not occur. The mean ± standard deviation operative time, including cervical bypassing, was 229 ± 48 minutes (IQR, 150-356 minutes). Twenty-five (89.3%) patients were extubated in the operating room. Double-side and single-side branched devices were used in 24 (85.7%) and 4 (14.3%) patients, respectively. For BCA, the Bolton cervical stent was used in 9 (32.1%) patients, Gore Excluder iliac leg in 17 (60.7%), and the Cook Zenith AAA iliac leg in 2 (7.1%). For the left CCA, we used the Bolton cervical stent in 7 (29.2%) patients, the Gore Excluder contralateral leg in 13 (54.2%), and the Cook Zenith AAA iliac leg in 2 (8.3%).



VIDEO 1. Overview of the Bolton branched endograft. The custom-made branched device is fundamentally similar to the Relay NBS device (Bolton Medical, Inc, Sunrise, Fla). This device has a large gate to cannulate the cervical devices easily, with 2 internal inner tunnels. Case: A 67-year-old man underwent the graft replacement of the ascending aorta due to type A dissection in 2004. A large entry exists at the distal side of the graft anastomosis and the false lumen has enlarged to 62 mm. We planned to perform total endovascular repair using the Bolton double-side branch system (Bolton Medical, Inc); the proximal and distal sizes are 36 mm and 26 mm, respectively. Procedure: Under general anesthesia, the patient receives an extra-anatomical bypass from the right axillary artery (AxA) to the left AxA or from the right AxA to the left common carotid artery (CCA) and the left AxA using a ringed 8-mm expanded polytetrafluoroethylene graft. The balloon catheter is then inflated at the orifice of the left subclavian artery to protect against emboli after the bypass. A pacemaker catheter is inserted for rapid-pacing. The rapid pacing is undergone while deploying the main branched graft. A straight wire is used to cross the aortic valve and advanced to the left ventricle. This was then exchanged for a curved super-stiff wire. Dyna-computed tomography is performed for 3-dimensional (3D) mapping. The main device is inserted through the right femoral artery approach. After delivering the device to the descending aorta, the flexible inner sheath is advanced to the aortic arch and then toward the ascending aorta. We confirm the precise match between the orifices of the cervical arteries and the device gate by performing standard angiography and 3D mapping. Rapid pacing (heart rate 180 bpm) is started, and the main body of the device is deployed at a constant speed. Next, the wire is advanced to the posterior tunnel from the right CCA, and the measurement catheter is advanced to this tunnel to select the cervical device. The stent-graft device for the brachiocephalic artery is inserted into the tunnel and deployed carefully, and touch-up ballooning is performed. For the left CCA, the same deployment procedure is performed for the double-side branched stent-graft. Lastly, we perform coiling of the left subclavian artery using the balloon catheter, which is inserted before deploying the stent-grafts. Aortography is conducted to check for endoleaks and bypass patency. Video available at: https://www.jtcvs.org/article/S2666-2507(20)30542-3/fulltext.

In 3 cases (10.7%), an additional stent-graft was used at the distal LZ; in 10 cases (35.7%), the filter devices were used in the cervical arteries to prevent intraoperative stroke. One patient (3.6%) had left ventricle rupture caused by the stiff wire. The median size and mean oversizing rate of the proximal stent-graft were 41.0 mm (IQR, 38.0-46.0 mm) and 120% ± 8%, respectively.

TABLE 1. Patient characteristics and preoperative measurement (N = 28)

Characteristic	Result
Age (y)	78.4 ± 6.9
Age ≥80 y	15 (53.6)
Male	17 (60.7)
Emergency	0
Aortic pathologies	
Degenerative aneurysm	22 (78.6)
Dissecting aneurysm	6 (21.4)
Preoperative complications	
Cerebrovascular disease	5 (17.9)
Coronary artery disease	7 (25.0)
CKD stage ≥4	6 (21.4)
COPD	10 (35.7)
EF	64.9 ± 8.7
Previous cardiovascular surgery (%)	14 (50.0)
Logistic EuroSCORE	38.8 (33.1-46.0)
EuroSCORE 2	6.6 (5.7-8.9)
Preoperative measurement	
Maximum aneurysm diameter (mm)	56.5 (54.3-60.8)
Diameter of proximal LZ (mm)	34.3 ± 3.6
Diameter of distal LZ (mm)	29.1 ± 3.4
Length of proximal LZ (mm)	34.6 ± 8.5
Atheroma grade of ascending aorta	
1	19
2	9
3	0
4	0
5	0
Atheroma grade of aortic arch	
1	1
2	6
3	15
4	5
5	1
Atheroma grade of descending aorta	
1	3
2	18
3	6
4	0
5	1
Atheroma grade of BCA	
1	22
2	6
3	0
4	0
5	0
Atheroma grade of left CCA	
1	25
2	3
3	0

(Continued)

TABLE 1. Continued

Characteristic	Result
4	0
5	0

Values are presented as mean ± standard deviation, n (%), median (interquartile range), or n. *CKD*, Chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *EF*, ejection fraction; *EuorSCORE*, European System for Cardiac Operative Risk Evaluation; *LZ*, landing zone; *BCA*, brachiocephalic artery; *CCA*, common carotid artery.

TABLE 2. Procedure and stent-graft (N = 28)

Variable	Result
Procedure success	28 (100)
Operative time (min)	229 ± 48
Extubation in operating room	25 (89.3)
30-d mortality	0
In-hospital mortality (%)	0
Procedure	
Double-side branched device and right AxA-left AxA bypass	24 (85.7)
Single-side branched device and right AxA-left CCA-left AxA bypass	3 (10.7)
Single-side branched device and right AxA-left CCA bypass	1 (3.6)
Main stent-grafts	
Size of proximal stent-graft (mm)	41.0 (38.0-46.0)
Size of distal stent-graft (mm)	35.0 (30.0-38.0)
Proximal stent-graft oversizing rate	120 ± 8
Distal stent-graft oversizing rate	117 ± 9
BCA stent-grafts	28 (100)
Bolton* cervical stent	9 (32.1)
Gore† Excluder contralateral leg	17 (60.7)
Cook Zenith‡ AAA iliac leg	2 (7.1)
Left CCA stent-grafts	24 (85.7)
Bolton* cervical stent	7 (29.2)
Gore† Excluder contralateral leg	13 (54.2)
Cook Zenith‡ AAA iliac leg	2 (8.3)
Additional procedures	
Distal TEVAR	3 (10.7)
Filter protection of cervical arteries	10 (35.7)
Intraoperative incidents	
Massive bleeding	0
LV rupture	1 (3.6)
Retrograde type A dissection	0
Any other dissection	0

Values are presented as n (%), mean ± standard deviation, or median (interquartile range). *AxA*, Axillary artery; *CCA*, common carotid artery; *TEVAR*, thoracic endovascular aortic repair; *LV*, left ventricular. *Bolton Medical, Inc, Sunrise, Fla. †W.L. Gore & Associates, Newark, Del. ‡Cook, Inc, Bloomington, Ind.

TABLE 3. Thirty-day and midterm outcomes (N = 28)

Outcome	Result
30-d complications	
Stroke	4 (14.3)
Transient neurologic dysfunction	2 (7.1)
Disabling stroke	2 (7.1)
Spinal cord injury	0
Cardiac events	0
Tracheostomy	1 (3.6)
Bowel ischemia	0
30-d aortic events	
Retrograde type A dissection	0
Aneurysm rupture	0
Stent-graft migration	0
Stent-graft-induced distal re-dissection	0
Stent-graft infection	0
Bypass graft occlusion	0
30-d endoleak	
Type 1a	0
Type 1b	0
Type 2	0
Type 3	0
Midterm complications	
Stroke	0
Spinal cord injury	0
Cardiac events	0
Bowel ischemia	0
Midterm aortic events	
Retrograde type A dissection	0
Aneurysm rupture	2 (7.1)
Stent-graft migration	2 (7.1)
Stent-graft-induced distal re-dissection	0
Stent-graft infection	0
Bypass graft occlusion	0
Midterm endoleak	
Type 1a	0
Type 1b	1 (3.6)
Type 2	0
Type 3	1 (3.6)
Aneurysm change	
Enlarge	2 (7.1)
No change	25 (89.3)
Shrinkage	1 (3.6)
Disappear	0

Values are presented as n (%).

Thirty-Day Outcomes

We did not note 30-day mortality or in-hospital mortality. Four (14.3%) patients developed symptomatic stroke. Two (7.1%) patients developed transient neurologic dysfunction as they recovered from cerebral infarction. Two (7.1%) patients had disabling stroke (modified Rankin scale ≥2). In

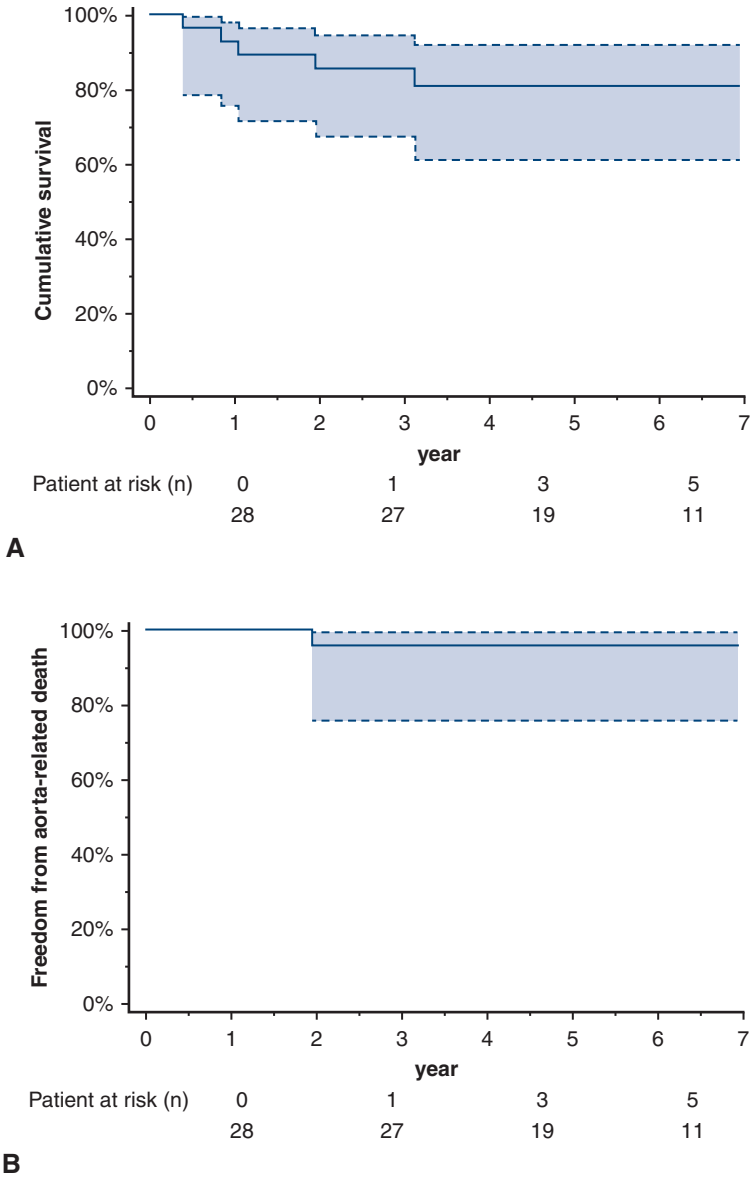


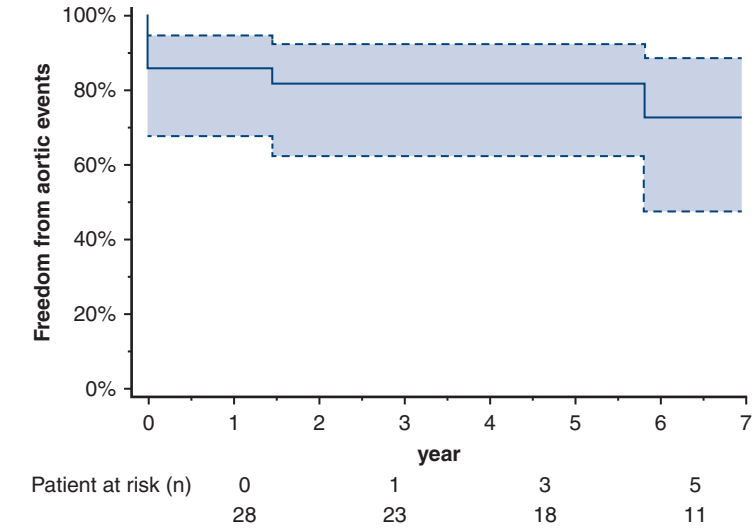
FIGURE 2. Kaplan-Meier curves. A, Cumulative survival. The cumulative survival rates at 1, 3, and 5 years are 92.7%, 85.6%, and 80.8%, respectively. B, Freedom from aorta-related death. The aorta-related death-free rates at 1, 3, and 5 years are 100%, 95.8%, and 95.8%, respectively. C, Freedom from aortic events. The aortic event-free survival rates at 1, 3, and 5 years are 85.7%, 81.6%, and 81.6%, respectively.

contrast, spinal cord injury and bowel ischemia due to emboli were not detected. One patient developed laryngeal edema after 1 week postoperatively requiring tracheotomy. No incidence of migration, collapse, or endoleak as stent-graft associated complications was reported (Table 3).

Midterm Outcomes

The cumulative survival rates at 1, 3, and 5 years were 92.7%, 85.6%, and 80.8%, respectively (Figure 2, *A*). There were 5 deaths during the follow-up period, including 1 (3.6%) patient who developed aneurysmal rupture post-operatively due to a type 1b endoleak at 1.5 years and then died 1.9 years later. The other 4 postoperative deaths were caused by cancer (1 case, at 3.1 years) and pneumonia (3 cases, at 0.4, 0.8, and 1.1 years, respectively). The aorta-related death-free rate at 5 years was 95.8% (Figure 2, *B*).

The aortic event-free survival rates at 1, 3, and 5 years were 85.7%, 81.6%, and 81.6%, respectively (Figure 2, *C*). During the follow-up period, there were 6 aortic events. Four (14.3%) patients had perioperative stroke and 2 (7.1%) patients had aneurysmal rupture due to type 1b endoleak at 1.5 years and type 3 endoleak at 5.8 years. They underwent additional TEVAR. Of these 2 patients, 1 patient with type 3 endoleak survived, whereas the other did not.



C

FIGURE 2. (Continued).

Cases of retrograde type A dissection, type 1a endoleak, other aortic events, or midterm complications, such as stroke, were not reported (Table 3).

Aneurysm changes are listed in Table 3. In most cases (25 out of 28 [89.3%]), there was no change in the aneurysmal diameter. Two patients (7.1%) with aneurysmal enlargement had endoleaks due to type 1b and type 3 endoleaks.

Stroke

The detailed characteristics of 4 (4 out of 28 [14.3%]) patients with perioperative stroke are listed in Table 4. Of the 4 patients, 2 (2 out of 28 [7.1%]) patients had disabling stroke. The numbers of patients with atheroma grade $\geq$2 in the BCA and left CCA were 6 (6 out of 28 [21.4%]) and 4 (4 out of 28 [14.2%]), respectively. Of these patients, 66.7% (4 out of 6) patients with atheroma grade $\geq$2 in the BCA and 25.0% (1 out of 4) patients with atheroma grade $\geq$2 in the left CCA had perioperative stroke. Filter devices of cervical arteries were used in 10 (10 out of 28 [35.7%]) patients. Of those, 2 (2 out of 10 [20.0%]) patients had disabling stroke (Table 5).

DISCUSSION

Zone 0 landing hybrid TEVAR without cardiopulmonary bypass for the aortic arch pathologies is less invasive than conventional open arch repair.[6,7] However, this procedure is still relatively invasive because median sternotomy and multiple cervical arterial bypasses are performed. In addition, the mortality rates of zone 0 landing TEVAR were 5% to 12% in previous studies, which is considered high.[1,4,8-13]

The fenestrated and the chimney graft technique were prevalently used for their minimal invasiveness and have substituted for the hybrid TEVAR procedure. The fenestrated devices are perforated in the cervical branch of the stent-graft that helps sustain blood flow to those areas. However, there are possible concerns of endoleaks from fenestrations after surgery and uncertain long-term outcomes.[14-17] Regarding the chimney graft technique, the overlap between the 2 devices in the proximal LZ creates a gutter between the stent-grafts, leading to a type 1a endoleak occasionally, which can prevent the completion of aortic treatment.[18-23]

TABLE 4. Characteristics of 4 patients with stroke

Case	Stroke	Age	Pathology	Atheroma grade					Device			Filter
				Asc Ao	Arch	Dec Ao	BCA	Left CCA	Main	BCA	Left CCA	
1	Transient	75	Degenerative	1	2	2	2	1	DS	B	B	No
2	Transient	66	Degenerative	1	2	3	2	1	DS	B	B	No
3	Disabling	84	Degenerative	1	4	2	2	1	DS	B	B	Yes
4	Disabling	73	Degenerative	2	3	2	2	2	SS	G	–	Yes

Asc Ao, Ascending aorta; *Dec Ao*, descending aorta; *BCA*, brachiocephalic artery; *CCA*, common carotid artery; *DS*, double-side branched device; *B*, Bolton (Bolton Medical, Inc, Sunrise, Fla) abdominal stent; *SS*, single-side branched device; *G*, Gore Excluder (W.L. Gore & Associates, Newark, Del) contralateral leg.

TABLE 5. Stroke

Characteristic	N	Stroke	Stroke
Preoperative characteristic			
Age ≥80 y	15	1	1/15 (6.7)
Gender: Male	17	2	2/17 (11.8)
Aortic pathologies: Degenerative	23	4	4/23 (17.4)
Cerebrovascular disease	7	2	2/7 (28.6)
Atheroma grade			
Ascending aorta ≥2	9	1	1/9 (11.1)
Aortic arch ≥3	21	2	2/21 (9.5)
Descending aorta ≥3	7	1	1/7 (14.3)
BCA ≥2	6	4	4/6 (66.7)
Left CCA ≥2	4	1	1/4 (25.0)
Device			
Main: Double-side branched device	24	3	3/24 (12.5)
Stent-graft of BCA: Bolton* cervical stent	9	3	3/9 (33.3)
Stent-graft of left CCA: Bolton* cervical stent	7	2	2/7 (28.6)
Filter protection	10	2	2/10 (20.0)

Values are presented as n or n/n (%). *BCA*, Brachiocephalic artery; *CCA*, common carotid artery. *Bolton Medical, Inc, Sunrise, Fla.

Therefore, device manufacturers developed branched devices for clinical applicability. Branched graft devices for aortic arch diseases, including custom-made devices have gained recent attention.[24-29] In this study, we used a Bolton branched endograft that has a large gate, which significantly facilitates the cannulation of cervical devices into the inner tunnel within the main device. This study did not detect 30-day mortality and in-hospital deaths, which were reported by some other studies.[30-33]

In this study, our midterm results were satisfactory because there were no cases of retrograde type A dissection, type 1a endoleak, and the aorta-related death-free rate at 5 years was 95.8%. However, the postoperative stroke rate reported in our study was 14% (4 out of 28), which was higher than that reported in previous studies (5% to 11.4%) with zone 0 landing TEVAR. This outcome is not better than the results of previous studies on zone 0 landing TEVAR, and it is not an acceptable result with regard to cerebral infarction.[4,8,9] We selected the patients who did not have a shaggy ascending aorta and BCA. Regarding the ascending aorta, our results show that the thrombus in the ascending aorta did not cause any significant difference in stroke. However, all patients with stroke had an atheroma grade ≥2 in the BCA. Cerebral infarction could have been caused by a stent-graft making contact with the atheroma during insertion of the cervical stent-graft and deployment of the stent-graft, resulting in atheroma embolism. For postoperative stroke prevention, the results of this study showed how important it is to conduct preoperative strict atheroma evaluation of the cervical arteries, especially. Study patients with atheroma grade ≥2 in the BCA may develop cerebral infarction after this procedure; therefore, at this time, we suggest that it is better to not perform TEVAR for these patients. Instead, graft replacement of the ascending aorta and cervical arteries should be performed using circulatory arrest and cardiopulmonary bypass to reduce the incidence of stroke. However, for patients who cannot tolerate such invasive surgery, minimally invasive surgery such as branched TEVAR is essential. Therefore, the development of a novel filter device for cervical arteries is imperative to prevent the cerebral infarction.

Concerning the use of this branched endograft device, it is imperative to carefully select patients without aortic thrombi, including the cervical arteries. Therefore, targeting aortic dissections in having cleaner aortic wall areas is advisable. In particular, the residual aortic dissection after ascending aortic graft replacement for acute type A aortic dissection may best indicate the need for TEVAR using a branched endograft.[34] In this study, no strokes occurred with TEVAR using a branched endograft for residual dissection. Additionally, the use of the filter device was not effective in this study. However, we assume that the use of the filter device might have prevented a cerebral infarction event according to the study by Shimamura and colleagues.[35] Hence, improvement of the filter device for the cervical arteries may prevent cerebral infarction.

Limitations

This study is the retrospective study and has a relatively small study size. Our study period also was limited because it did not include a long-term follow-up period. Therefore, a prospective multicenter study with a long-term follow-up is required to confirm our findings. Moreover, the findings of this study need to be validated by further clinical investigations.

CONCLUSIONS

We achieved satisfactory early and midterm results of performing TEVAR using the Bolton branched endograft, which did not require complex aortocervical bypass or graft replacement procedures. This study demonstrated the importance of conducting preoperative strict atheroma evaluation to prevent postoperative stroke, which is the most serious complication. Although long-term results, a larger study size, and strict evaluation of preoperative atheroma to prevent postoperative stroke are needed, TEVAR using the Bolton branched endograft may be considered among the less-invasive treatments for aortic arch pathologies.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict

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Key Words: endovascular graft, endovascular procedure, aortic arch aneurysm, stroke