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

Tomoaki Kudo, MD, PhD,a Toru Kuratani, MD, PhD,b Kazuo Shimamura, MD, PhD,b and Yoshiki Sawa, MD, PhDa

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)

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.
Aortic arch pathologies are extremely difficult to treat because they require conventional open surgeries, which are highly invasive and complex procedures.\(^1\,^2\,^3\) 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).

### METHODS

#### 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

#### 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 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. DynaCT 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 ± standard deviation and median (interquartile range [IQR]) according to the normality of the distribution, as
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 Euro- 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 branched endograft 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%).
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                       |

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.
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).
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 postoperatively 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.
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 ≥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 ≥2 in the BCA and 25.0% (1 out of 4) patients with atheroma grade ≥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).

### TABLE 4. Characteristics of 4 patients with stroke

| Case | Stroke  | Age  | Pathology    | Atheroma grade | Device   |
|------|---------|------|--------------|----------------|----------|
|      |         |      | Asc Ao | Arch | Dec Ao | BCA | Left CCA | Main  | BCA | Left CCA | Filter |
| 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.

**DISCUSSION**

Zone 0 landing hybrid TEVAR without cardiopulmonary bypass for the aortic arch pathologies is less invasive than conventional open arch repair. 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.

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. 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.
TABLE 5. Stroke

| Characteristic                      | N | Stroke | Stroke |
|------------------------------------|---|--------|--------|
| Patient characteristics            |   |        |        |
| 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. 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.

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. 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. 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. 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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