Aortic Arch Reconstruction by Transluminally Placed Endovascular Branched Stent Graft

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Background—Recently, thoracic aortic stent grafting has emerged as an alternative therapeutic modality for patients with thoracic aortic aneurysms and aortic dissections. However, its application has been limited to descending thoracic aortic aneurysms distal to the aortic arch. We report our initial clinical experience of endovascular branched stent graft repair for aortic arch aneurysms.

Methods and Results—Endovascular grafting with Inoue branched stent grafts was attempted for 15 patients with thoracic aortic aneurysms and aortic dissections under local anesthesia (n=14) or general anesthesia (n=1). Single-branched stent grafts were used in 14 patients, and a triple-branched stent graft in one. The branched stent grafts were delivered through a 22F or a 24F sheath under fluoroscopic guidance and implanted across the aneurysmal aortic arch. In 2 patients, the single-branched stent graft did not pass through the 22F sheath used. Complete thrombosis of the aneurysm was ultimately achieved in 11 patients (73%). Of 4 persistent leaks, 1 minor leak spontaneously thrombosed and 1 major leak was successfully treated by additional straight stent graft placement. In 1 patient, the right external iliac artery ruptured during the withdrawal of the sheath and was successfully repaired by the implantation of a straight stent graft. One patient with severe stenosis of the aortic graft section was successfully managed by additional stent deployment. Peripheral microembolization to a toe occurred in 1 patient, and cerebral infarction occurred in 1 other patient. Two patients who had failed to receive endovascular stent grafts died during an average follow-up of 12.6 months, 1 of pneumonia and the other of rupture of a concomitant abdominal aortic aneurysm.

Conclusions—This report demonstrates the technical feasibility of endovascular branched stent graft repair for aneurysms located at the aortic arch. Careful, longer follow-up and further extensive clinical trials are awaited toward establishing this technique as a recommendable alternative to surgical treatment of thoracic aortic aneurysms. (Circulation. 1999;100[suppl II]:II-316-II-321.)

Key Words: aneurysm ■ vessels ■ aorta ■ stents ■ grafting

The leading cause of death for patients with surgically untreated thoracic aortic aneurysms is ruptured aneurysm.1–3 Currently, the standard treatment of thoracic aortic aneurysms is surgery with artificial graft replacement, for which perioperative mortality rates of 5% to 35% have been documented in multicenter reports.4–10 The surgical treatment has achieved remarkable advancement due to the introduction of deep hypothermic circulatory arrest and myocardial protection with cardioplegic solution. Despite recent progress of thoracic aortic surgery, complications are still prevalent in repair of aortic arch aneurysms, especially in patients with advanced age and coexisting morbid conditions.4,11,12 Recently, catheter-based strategy for the treatment of coronary heart disease and valvular heart disease has progressed dramatically.13 Therefore, the development of new, minimally invasive treatment for aortic aneurysms is desired.

Transluminal endovascular stent graft placement has recently been introduced as a promising alternative to surgical treatment of aortic aneurysms. For thoracic aortic aneurysms, Dake and colleagues first reported the clinical feasibility of endovascular repair with Dacron-covered, self-expanding, stainless steel straight stent grafts in 13 cases with descending thoracic aortic aneurysms in 1994.14 However, only 8% of their patients with thoracic aortic aneurysms was suitable for endovascular repair with straight grafts. Endovascular stent graft placement requires satisfactory landing zones. Therefore, the development of branched stent grafts has been eagerly awaited for treating aortic arch aneurysms, with perfusion of the great vessels arising from the aneurysmatically arch preserved. We present our initial experience with transluminally placed endovascular Inoue branched stent grafts for the treatment of thoracic aortic aneurysms.

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elaborately investigated with these diagnostic modalities. Aortic side branches and identification of their lumen of origin were performed because they had a large aortic diameter (range, 21 to 84). Seven patients (47%) were judged to be at high risk for conventional surgical repair because of age ≥70 years (n=5) and/or coexisting morbid conditions. The remaining 8 patients who had rejected open surgery were referred to the 2 study hospitals because of their desire for endovascular therapy. Associated nonaortic diseases were coronary artery disease in 2 patients, chronic obstructive pulmonary disease in 1, cerebrovascular lesions in 4, renal failure in 1, and diabetes mellitus in 1. One patient had a previous operation on the thoracic aorta. Atherosclerotic, traumatic and false aneurysms, and aortic dissections were included. The mean diameter of the aneurysms was 57.4 mm. All patients of aortic dissections were treated at the chronic stage. Acute aortic dissections were excluded. Of 7 patients with aortic dissections, 6 had Stanford type B aortic dissection with primary tears close to the origin of the left subclavian artery. For these patients, the stent grafting was performed under general anesthesia in the angiography suite. The single-branched stent graft was placed into the distal aortic arch including the origin of the left subclavian artery and the descending thoracic aorta. One patient with diffusely aneurysmal transverse aortic arch received a triple-branched stent graft which had sidearms extending into the right brachiocephalic, the left carotid, and the left subclavian arteries. Both the proximal and distal landing zones should measure at least 1 cm in length. For placement of the single-branched stent graft, the length of the proximal landing zone was especially important. Ideally, the front part of the proximal landing zone, the segment between the origin of the left subclavian artery and the left carotid artery, and the back part of the proximal landing zone, the segment between the origin of the left subclavian artery and the proximal aspect of the aneurysm, should each be >5 mm in length.

Implantation Technique
Fourteen procedures with single-branched stent grafts were performed under local anesthesia, and one procedure with a triple-branched stent graft was performed under general anesthesia in the angiography suite. The single-branched stent graft was placed into the distal aortic arch including the origin of the left subclavian artery and the descending thoracic aorta. One patient with diffusely aneurysmal transverse aortic arch received a triple-branched stent graft which had sidearms extending into the right brachiocephalic, the left carotid, and the left subclavian arteries. Both the proximal and distal landing zones should measure at least 1 cm in length. For placement of the single-branched stent graft, the length of the proximal landing zone was especially important. Ideally, the front part of the proximal landing zone, the segment between the origin of the left subclavian artery and the left carotid artery, and the back part of the proximal landing zone, the segment between the origin of the left subclavian artery and the proximal aspect of the aneurysm, should each be >5 mm in length.

Methods
Patients
From May 1995 to April 1998, endovascular grafting with the Inoue branched stent graft was attempted in 15 patients with aortic arch aneurysms at Takeda Hospital, Kyoto, Japan, and National Toyohashi East Hospital, Aichi, Japan. All patients gave their informed consent in conformance with the protocols approved by the institutional review board of each hospital. There were 12 men and 3 women with a median age of 61 years (range, 21 to 84). Seven patients (47%) were judged to be at high risk for conventional surgical repair because of age ≥70 years (n=5) and/or coexisting morbid conditions. The remaining 8 patients who had rejected open surgery were referred to the 2 study hospitals because of their desire for endovascular therapy. Associated nonaortic diseases were coronary artery disease in 2 patients, chronic obstructive pulmonary disease in 1, cerebrovascular lesions in 4, renal failure in 1, and diabetes mellitus in 1. One patient had a previous operation on the thoracic aorta. Atherosclerotic, traumatic and false aneurysms, and aortic dissections were included. The mean diameter of the aneurysms was 57.4 mm. All patients of aortic dissections were treated at the chronic stage. Acute aortic dissections were excluded. Of 7 patients with aortic dissections, 6 had Stanford type B aortic dissection with primary tears close to the origin of the left subclavian artery. For these patients, the stent grafting was performed because they had a large aortic diameter (>50 mm), chronic-phase progressive dilation of the dissected aorta, or recurrent aortic dissection. The remaining patient had an aortic arch aneurysm following Stanford type A aortic dissection. Simultaneous reconstruction of the distal arch including the origin of the left subclavian artery and the descending thoracic aorta with single-branched stent grafts was attempted in 14 patients and total arch reconstruction with a triple-branched stent graft in one. All patients underwent arteriography and helical CT with 3D vascular reconstruction before the procedure. For patients with aortic dissection, involvement of the aortic side branches and identification of their lumen of origin were elaborately investigated with these diagnostic modalities.

Endoprostheses
The Inoue stent graft was constructed from a woven Dacron polyester fabric cylinder (Figure 1). The outside surface of the stent graft was supported by multiple rings of extraflexible wire. With the latter modification, the sealing function was notably improved. The length, diameter, and taper of the stent graft, and the suitable landing zone were determined on the basis of information obtained by helical CT with 3D vascular reconstruction and multiplanar reconstruction. The diameter of the stent graft was 1 to 3 mm larger than the diameter of the landing zones of native aorta. The stent grafts were custom-made and were individually designed for each patient. The size of the aortic graft section was 22 to 40 mm in diameter and 50 to 250 mm in length. The branched graft section was 7 to 17.5 mm in diameter and 12 to 30 mm in length.

Implantation Technique
Fourteen procedures with single-branched stent grafts were performed under local anesthesia, and one procedure with a triple-branched stent graft was performed under general anesthesia in the angiography suite. The single-branched stent graft was placed into the distal aortic arch including the origin of the left subclavian artery and the descending thoracic aorta. One patient with diffusely aneurysmal transverse aortic arch received a triple-branched stent graft which had sidearms extending into the right brachiocephalic, the left carotid, and the left subclavian arteries. Both the proximal and distal landing zones should measure at least 1 cm in length. For placement of the single-branched stent graft, the length of the proximal landing zone was especially important. Ideally, the front part of the proximal landing zone, the segment between the origin of the left subclavian artery and the left carotid artery, and the back part of the proximal landing zone, the segment between the origin of the left subclavian artery and the proximal aspect of the aneurysm, should each be >5 mm in length.

The implantation technique of the single-branched stent graft has been previously described in detail. Figure 2 shows how to implant the single-branched stent graft. A detachable carrying wire was attached to the proximal end of the aortic graft section and a detachable traction wire was also attached to each distal end of the aortic and branched graft sections. Before the insertion of the stent graft, the aortic graft section and the branched graft section were individually folded using loops of thread and nickel titanium wires in
such a way that the stent graft should not spontaneously expand after its release from the sheath.

After initial arteriography, 200 U of heparin sodium per kilogram of body weight were administered. A 22F or 24F Teflon sheath was introduced into the descending thoracic aorta through a femoral arteriotomy under fluoroscopic guidance. The folded branched stent graft, with the aid of its carrying system, was introduced within the sheath, advanced to the descending aorta, and was released from the sheath. With a carrying wire, the folded graft was then advanced to the distal arch. The free end of the traction wire attached to the tip of the branched graft section was caught and pulled back by a gooseneck snare wire, which was inserted percutaneously through the left brachial artery. Once the aortic graft section and the branched graft section were properly positioned by manipulating the carrying wire and both traction wires, the aortic and branched graft sections were unfolded by removal of each nickel titanium wire. Finally, both sections of the branched stent graft were dilated by balloon inflation. An intra-aortic balloon pumping system was used for balloon inflation of the aortic graft section. Immediately after the stent graft placement, arteriography was performed to confirm the stent graft position and the exclusion of the aneurysm. After completion of arteriography, all delivery systems were removed, the arteriotomy was repaired, and the effect of heparin was neutralized with protamine sulfate.

The triple-branched stent graft was implanted in a manner similar to that used for the single-branched stent graft. The compactly folded stent graft was delivered to the descending thoracic aorta via a 24F sheath, released from the sheath, and then advanced into the ascending aorta with the aid of a carrying wire. Then, each branched graft section was positioned, one by one, into the aortic branch by drawing the traction wire attached to its tip with the aid of a gooseneck snare wire (inserted percutaneously through the bilateral brachial arteries and the left carotid artery). After all sections of the stent graft were unfolded, the branched stent graft was pressed against the aortic and arterial walls by balloon inflation.

Follow-Up Protocol
All patients were followed up with contrast enhanced helical CT or arteriography, or a combination of these before discharge within 1 month after the procedure. These examinations were then repeated at 6 months and every subsequent year.

Results
Primary success, defined as a complete exclusion of the aneurysm from the circulation at the time of the first postoperative CT or arteriography, was achieved in 9 patients (60%) (Figure 3). In 2 patients, the branched stent graft did not pass through the 22F sheath used. This failure was due to marked tortuositities and small diameters of the iliac arteries.
These patients were subjected to medical treatments because they were considered to be ineligible for a conventional open surgical graft replacement. Follow-up studies demonstrated 2 minor and 2 major persistent leaks in 4 patients. The 1 minor proximal leak spontaneously thrombosed by 15 months after the procedure, and helical CT scans of the thoracic aorta have shown that the aneurysm substantially shrank with disappearance of the leak. Another minor leak has been under continual careful observations. In 1 patient who received a triple-branched stent graft for a diffusely aneurysmal aortic arch following Stanford type A dissection, the first follow-up helical CT before discharge revealed a major persistent peri-graft leak. The leak originated from the distal end of the brachiocephalic graft section. The leak was sealed with an additional short straight stent graft, which was placed to the distal brachiocephalic artery in a manner overlapping the earlier placed branched graft section. On a follow-up contrast-enhanced CT obtained 1 month after the second procedure, a small amount of localized contrast enhancement in the aneurysm sac was noted. It was deemed to be retrograde reperfusion from small vessels of the aortic aneurysm, but the feeding artery was not detected. Seven months after the procedure, the follow-up CT scan demonstrated a reduction in the diameter of the aneurysm sac. Another patient with a major persistent peri-graft leak had a large focal sacciform aneurysm located at the lesser curvature of the distal arch. In this case, the proximal landing zone was very short. The proximal end of the aortic graft section was placed into the aneurysm sac by the inadvertent operation of a carrying wire, causing a major proximal leak. Although endovascular grafting with a triple-branched stent graft seemed to be best to repair the aneurysm, this technique had not been developed at that time. The patient has declined further intervention. In sum, complete aneurysm thrombosis was eventually accomplished in 11 patients (73%).

Severe graft stenosis occurred in 1 patient at the aortic section of a single-branched stent graft during the procedure. The aortic graft section was twisted during the insertion of the branched graft section into the left subclavian artery. The graft was successfully corrected by deployment of additional 2 Palmaz stents with a diameter of 8 mm. The Palmaz stents placed within the stent graft were inflated using an 18-mm diameter balloon. The patient had also a mild stenosis of the branched graft section at the left subclavian artery origin. Although the blood flow through the branched graft section did not appear to be impeded on fluoroscopy, a Palmaz stent was placed as a preventive management against graft thrombosis.

Cerebral infarction occurred in 1 patient, who received a single-branched stent graft, because of multiple cerebral embolism into the vertebral artery and severe stenosis of the left carotid artery resulting from a layout error of the stent graft. Most of the carotid ostium was covered by the stent graft because the length from the proximal edge to the sidearm of the stent graft was too long. She gradually recovered and was able to walk with a cane on discharge. Peripheral thrombomicroembolism of the toe was encountered in 1 patient with a coexistent abdominal aortic aneurysm during the delivery of the sheath. In this case, preexist-

ing renal dysfunction was also aggravated. Whether the aggravation was because of embolization to the kidneys or potential side effects of the contrast medium was not evident. In 1 patient, the coiled right external iliac artery ruptured during the withdrawal of the delivery sheath; it was successfully repaired by the implantation of a straight stent graft. Pseudoaneurysm developed in 1 patient at the site of the percutaneous puncture of the right brachial artery required surgical intervention. Acute thrombosis developed in 1 patient at the puncture site of the left brachial artery and was successfully managed by Fogarty catheterization.

The average length of follow-up is currently 12.6 months (range, 5 to 35 months). There were 2 late deaths which occurred to the patients with aborted endovascular stent grafting. The first resulted from rupture of a concomitant abdominal aortic aneurysm that was not contiguous with the thoracic aortic aneurysm at 6 months after the procedure. The second death was due to pneumonia at 1 year. No other patients have shown any serious complications (eg, rupture and recurrence of the thoracic aortic aneurysm, migration and destruction of the stent graft, and significant graft stenosis).

Discussion

Although conventional surgical methods have thus far been the only treatments to prevent rupture of aortic aneurysms, transluminally placed endovascular stent graft has currently emerged as a new therapeutic strategy for aortic aneurysms. Compared with surgery, endovascular grafting is associated with shortened hospital stays, reduced patient discomforts, and potentially lower costs. The initial description of the concept of endovascular stent grafting for the treatment of aortic lesions was written in 1969,17 thus the clinical feasibility of the endovascular repair of abdominal aortic aneurysms, descending thoracic aortic aneurysms, and arteriovenous fistula with various stent graft devices has been repeatedly demonstrated in well-selected patients.14,18,19

The Inoue endovascular stent grafting differs substantially from other techniques in its innovative approach to accomplish the endovascular exclusion of thoracic aortic aneurysms. Earlier devices were simply pushed to the optimal position through the delivery sheath and then deployed by pulling back the sheath in position. With such a method, however, it is sometimes difficult to control with precision stent graft deployment; the irreversible nature of stent graft deployment may result in occlusion of major aortic branches arising from the ascending aorta and the transverse arch. In addition, for reducing the risk of stent graft migration, the blood pressure has to be considerably decreased with intravenous administration of vasodilator and β-blocker drugs just before the stent graft is released from the sheath.

The Inoue stent graft is delivered through the sheath with the aid of the detachable carrying and traction wires. The stent graft is released from the confines of the sheath in the folded state and it can be moved easily to desired position using the both wires even after its release from the sheath. These technical differences allow the precise positioning of the stent graft to the optimal position. In addition, the stent graft is flexible enough to conform to the curved aortic arch. Another technically advantageous innovation is the use of an
branched stent graft placement. At present, results of distal arteriosclerotic aneurysms can be treated with single-intimal tear just beyond the left subclavian artery, and B aortic dissections, which are usually accompanied by deaths directly attributable to the procedure have occurred. Therefore, one may ask whether our new technique could be as safe as, or safer than, surgery. In the present study, no deaths directly attributable to the procedure have occurred.

Our initial experience using the Inoue branched stent graft yielded a high success rate. The delivery failure encountered in 2 patients was related to a large profile of the branched stent graft. This is one of the important problems that must be solved. Although our current policy is to use iliac or aortic access when common femoral access is impossible, it will be necessary to add additional improvements to this device for minimizing its profile. The possibility of inducing microembolism has to be generally kept in mind because this device is manipulated in aortic arch aneurysms containing mural thrombus and diseased aortic branches. With our technique, the branched stent graft is released from the sheath and is delivered to the target position using a carrying wire; it is compactly folded, and insertion of the branched graft section into the aortic branch is actively steered by an easily manageable maneuver. Therefore, the occurrence of massive microembolization may be rare. However, in the present study, we had one embolic cerebrovascular accident. The accident occurred during the manipulation to correct the orientation of the stent graft, which was released upside down from the sheath. On the basis of this experience, a built-in curve was introduced into the branched stent graft itself so that it should naturally fit the greater and lesser curvatures of the aortic arch on its release from the sheath. After the improvement of the stent graft design, thromboembolic accidents have been circumvented.

The use of branched stent grafts enables extensive endovascular aneurysm repair. The majority of Stanford type B aortic dissections, which are usually accompanied by intimal tear just beyond the left subclavian artery, and arteriosclerotic aneurysms can be treated with single-branched stent graft placement. At present, results of distal aortic arch surgery for aneurysms and dissections are excellent and their operative mortality and morbidity are low. Therefore, one may ask whether our new technique could be as safe as, or safer than, surgery. In the present study, no deaths directly attributable to the procedure have occurred.

Our initial applications of the Inoue single-branched stent graft were favorable, and the implantation technique appears to be a promising method. Furthermore, we have demonstrated the technical feasibility of triple-branched stent graft placement (Figure 4). However, the patient had a peri-graft leakage from the distal end of the brachiocephalic graft section because of the inadequate graft size. For successful triple-branched stent grafting, a much more detailed and prudent preoperative evaluation would be crucial. The most important anatomical features are the diameter and length of the aneurysm neck and great vessels arising from the aortic arch and the positional relationship between each vessel and aorta. Contrast-enhanced helical CT is the primary imaging modality for an accurate design of the stent graft. However, the triple-branched stent graft design may be difficult because of the wide variability in aneurysm morphology. Therefore, the development of a computer-aided design system of the stent graft will be desired in the future to determine accurate sizing of the stent graft without great effort.

An ideal endovascular stent graft must be versatile enough to treat various types of thoracic aortic aneurysms. To achieve this, the development of branched stent grafts with an adequate dimensional adaptability is indispensable. Although the immediate and mid-term results of endovascular repair with the Inoue branched stent graft among patients with aortic arch aneurysms appear to be acceptable, long-term effectiveness remains to be demonstrated. We consider that the true success of endovascular stent graft repair is determined by long-term results. Therefore, rigorous long-term follow-up and further extensive clinical trials are needed before this method can become the primary treatment for thoracic aortic aneurysms.

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References
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