Usefulness of fenestrated stent grafts for thoracic aortic aneurysms†

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Abstract

OBJECTIVES: Endovascular stent grafts (SGs) comprise a novel therapeutic approach to repairing aortic aneurysms. However, endovascular repair of the aortic arch remains challenging. Generally, the repair of sites with SGs requires an extra-anatomical bypass. We introduced SG repair of the aortic arch with strategically positioned fenestrations for each arch branch in 2006. An extra-anatomical bypass is not required for this procedure. This study evaluates the early and mid-term outcomes of fenestrated SG treatment.

METHODS: We retrospectively analysed the early and mid-term outcomes of 24 of 80 repairs with fenestrated SG among 383 single thoracic aortic aneurysm repairs that were undertaken at our department between January 2006 and March 2012.

RESULTS: Technical success was obtained in 100% of the patients. However, there was a 30-day perioperative mortality rate of 4.1% (1 of 24) due to a shower embolism. One patient developed a Type 2 endoleak without aneurysm enlargement within a median follow-up time is 25.1 months. However, migrations or device-related complications requiring additional procedures did not arise.

CONCLUSIONS: Treatment with fenestrated SGs does not require surgical transposition of the arch branches. The procedure is widely applicable and less invasive and outcomes are excellent.

Keywords: Fenestrated stent graft • Endovascular repair • Thoracic aortic aneurysm

INTRODUCTION

The introduction of endovascular stent graft (SG) technology has ushered in a new era for the treatment of thoracic aortic aneurysms (TAAs) of the distal aortic arch and descending thoracic aorta [1, 2]. Thoracic endovascular aortic repair (TEVAR) is commercially available and has recently become popular worldwide. However, in Japan, the distal aortic arch is the most common site of TAA [3], and it remains a challenging area for endovascular repair because of anatomical restrictions and the presence of vital branches to the head and arms. The repair of these sites with SG usually requires an extra-anatomical bypass [4].

We also introduced TEVAR for high-risk patients undergoing surgery requiring thoracotomy at our medical centre and an associated institution. However, suitable commercialized SG devices for repairing arch aneurysms are not available [5]. We therefore introduced next-generation customized fenestrated SGs (FSGs) in 2006 for patients at high risk of aortic arch aneurysms.

We describe here the features and retrospective early and mid-term outcomes of the FSG.

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ETHICS

The FSG treatments in this study and this study protocol were approved by our institutional review board.

MATERIALS AND METHODS

We reviewed the records of 383 patients who had undergone single TAA repair in our department between January 2006 and March 2012. Among them, 24 of the 80 patients who had undergone SG had a FSG deployed at the aortic arch. The proximal ends of the SG were located in Ishimaru landing zones 0, 1 and 2 [1] in 19, 4 and 1 patients, respectively [6]. The left subclavian arteries were simply occluded in 13 patients. A left-right subclavian bypass was performed in 3 patients because of a hypoplastic right vertebral artery and a history of coronary artery bypass grafting (CABG) with a patent left internal mammary artery (LIMA). The left subclavian artery (LSA) was preserved in the other 8 patients. All early and mid-term outcomes were retrospectively analysed. The primary endpoints of the study were the technical success, defined as planned accurate deployment of the FSG without collapse and initial success defined as the absence of Type 1 or 3 endoleaks.
The secondary endpoints comprised Type 1 and 3 endoleaks, sac enlargement, mortality and morbidity rates and aneurysm-related complications at a median follow-up time of 25.1 months.

**Surgical indications**

All patients underwent preoperative contrast-enhanced multi-layered computed tomographic (CT) imaging to assess the feasibility of endovascular repair and the endograft size and to identify the optimal implantation strategy. Table 1 describes the anatomical criteria for FSG. The exclusion criteria included proximal and distal landing zones of <20 mm in length, a landing diameter <20 mm and >38 mm, all supra-aortic branches adhering to the aneurysmal wall and a severely tortuous or calcified arch.

Basically, open surgery was the first choice for TAA at our institution. However, the risk of complications was not only based on anatomical indications, but also the general patient status, comorbidities and general impression. Therefore, FSG was recommended for high-risk patients with comorbidities, such as previous cardiac and thoracic surgery, pulmonary insufficiency, liver cirrhosis, connective tissue disease, a history of mediastinal radiotherapy and malignancy. Additionally, we regarded not only comorbidities, but also frailty, cognitive impairment and disability as important factors [7]. In this study, patients with any deficiency in the Katz index of independence in activities of daily living [8], in ambulation or with a cognitive impairment were defined as frail and were considered to be indicated for FSG. As shown in Table 2, in the early period, we had 2 young patients, aged 17 and 37 years, respectively. These cases had rapidly expanding traumatic aneurysms. Both cases had a tracheostomy and neurological disorder. The Katz index of both cases was 0 points. These conditions forced us to perform FSG for these patients.

Therefore, the final indications for FSG included procedural safety, complication, long-term potential success rates and patient requests, without an age limitation (Fig. 1).

**Preoperative planning**

Our customized TEVAR device comprised a self-expandable stainless-steel Z-stent and an expanded polytetrafluoroethylene (e-PTFE) graft with customized fenestrations strategically positioned to suit individual vessel anatomy (Fig. 2). We have more than 10 types of precurved stainless-steel stent frames and several types of J-shaped sheaths (Fig. 3A and B). By combining these in various ways, we can create >100 varieties of FSG based on a review of preoperative images of aneurysms. An e-PTFE graft is located outside of a stent frame. Therefore, when the e-PTFE graft receives blood flow, it expands enough and fits snugly into the vascular intima.

All patients underwent a preoperative evaluation using multi-slice (<1 mm) contrast-enhanced CT. The anatomical details of each arch were analysed from all angles in three-dimensional CT (3D-CT) images to predict the route of the sheath and movement of the FSG at deployment. In addition, the device length, proximal and distal landing diameters and fenestration position were estimated using CT (Fig. 3C).

The Circle of Willis was routinely examined by magnetic resonance angiography, and the carotid and vertebral arteries were routinely examined by ultrasonography to confirm the presence of abnormalities of the intracranial artery and its communication routes. When the LSA was strategically occluded, forward flow of the vertebral artery seemed necessary, whereas undetectable forward flow indicated a need for revascularization of the LSA. The patients were routinely assessed by cardiac ultrasonography and coronary 3D-CT.

**Surgical procedures**

Fenestrated stent grafting proceeded with arterial blood pressure and electrocardiographic monitoring under general anaesthesia. A central venous catheter was inserted from the right jugular vein, and the left side of the neck was also sterilized without an infusion line, in case an emergency left carotid bypass was required.

A retrograde approach was applied for all patients. A femoral artery was surgically isolated and a 6-Fr sheath was inserted into the right brachial artery. The common iliac artery was used for conduit graft access when the femoral artery was too small for sheath insertion. The FSG was delivered with a 21- to 23-Fr J-shaped sheath by the ‘tug-of-wire’ technique [9]. Thereafter, the FSG was deployed at the planned position under fluoroscopic guidance without additional circulatory support. Accurate device positioning was assured by baseline digital subtraction angiography (DSA) before deployment.

Figure 4 shows the intraoperative FSG procedure for an aortic arch aneurysm. In such lesser-curve side aneurysms (such as in Fig. 4), the FSG can provide the maximum performance, because it can obtain a 3D sealing zone from the fenestration to the aneurysms.

The FSG is gradually opened during deployment and pushed along the greater curve of the aortic arch using the force of the blood flow, without blood-pressure control, which helps to prevent endoleaks and SG migration [10]. Post-deployment touch-up ballooning was performed as required. The LSA was revascularized in selected patients. Our indications for reconstruction comprised post-CABG status with a patent left internal mammary artery (LIMA)–left anterior descending artery (LAD) and an inadequate right vertebral artery. We also performed a reconstruction in a case at high risk for spinal-cord ischaemia due to long-segment treatment (the distal end of the SG is beyond Th10). A final DSA image was acquired to check for endoleaks and complete exclusion of the aneurysm.

**Follow-up and statistical analysis**

The postoperative follow-up chest X-ray and CT assessments were performed on an outpatient basis at 1, 3 and 6 months,
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<th>Aneurysm type</th>
<th>Aneurysm diameter (mm)</th>
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fluoro: fluoroscopy; M: male; F: female; FA: femoral artery; CIA: common iliac artery; HOT: house oxygen therapy; Pre Surg: previous cardiac and thoracic surgery; Malig: with malignancy; Cog: cognitive impairment; RTX: history of mediastinal radiotherapy; CTD: connective tissue disease; LC: liver cirrhosis.
and annually thereafter. The intermediate all-cause mortality and aneurysm-related events were statistically analysed using the Kaplan–Meier method, and all data were analysed using the Stat View software program (SAS, Inc., Cary, NC, USA).

RESULTS

Early technical and clinical outcomes

Table 2 shows the patients’ characteristics. In this table, the patients’ comorbidities and logistic EuroSCORE are described as references. The average age of the patients was 69 ± 15 years. A transfemoral approach was performed in 22 patients, and an iliac conduit was used in 2. Thirteen patients had a simply occluded LSA artery, and LSA revascularization and preservation were required for 3 and 8 patients, respectively. The mean durations of surgery and fluoroscopy were 164 ± 57 (without LSA revascularization and conduit access, 140 ± 27 min) and 24 ± 8 min, respectively. Technical success was obtained in 100% of the patients. However, there was a 30-day perioperative mortality rate of 4.1% (1 of 24) due to a shower embolism. No other cerebrovascular events occurred, but 1 patient developed temporary paraparesis that was reversible after cerebrospinal fluid drainage.

Follow-up and late outcomes

One Type 2 endoleak without aneurysm enlargement occurred at a median follow-up time of 25.1 ± 17 months (range 1.8–62.5 months). No Type 1 or 3 endoleaks occurred, and the incidence of endoleaks at follow-up was 4.3% (1 of 23). Furthermore, migrations or device-related complications requiring additional procedures did not occur.

The mid-term actuarial survival rate was 79.2% (20 of 24) at a median follow-up time of 25.1 months (Fig. 5). Excluding surgery-related death, 1 and 2 patients died of respiratory failure and malignancy, respectively, during this period. Thus, no deaths were associated with aortic aneurysms.

DISCUSSION

Stent grafting has become the most rapidly developing technology for treating aortic diseases over the past decade. Conventional surgery for TAAs consists of cardiopulmonary bypass with a major
incision, but this is invasive and major complications frequently arise. The incidence of morbidity and mortality after conventional open thoracic aortic surgery with brain perfusion and cardiopulmonary bypass ranges from 2.7 to 28.6% [11–13]. For reference, at our institution, according to the already-mentioned algorithm, we performed 168 total arch replacements during the same observational period. The mortality rate was 4.7% (8 patients died), and the neurological injury rate was 6.5% (11 cases). Furthermore, many patients are deemed unsuitable owing to serious comorbidities and frailties, and as a consequence, a less-invasive approach...
would be even more favourable to these patients. The benefits of SG, particularly TEVAR, are inestimable from this viewpoint.

Many manufacturers have developed SG to treat thoracic aneurysms. However, most of these devices were designed to treat aneurysms of the descending aorta. The anatomical indication for aortic arch disease remains limited by the angulated and complex morphological features, as well as by the involvement of the supra-aortic branches. Several strategies have been proposed to overcome these problems. The most popular is hybrid (open and endovascular) therapy that involves prophylactic transposition or bypass graft placement to provide blood flow to both the brain and arms. Therefore, an extra-anatomical bypass is sometimes required when distal arch aneurysms are treated. Recent reports have described hybrid aortic arch repair with a chimney technique [14], surgical debranching with thoracotomy and extra-anatomical bypass without thoracotomy [15]. Some published series of hybrid repairs of the thoracic aorta have included elective procedures, and some describe overall complications in landing zones 0, 1 and 2. The overall early outcomes of these hybrid methods had rates of mortality, stroke and endoleaks of 9–23.7, 0–13.2 and 3.7–13.2%, respectively [11, 16, 17]. Only one report has so far described the mid-term results [18]. Therefore, the outcomes require confirmation over the long term.

In this study, we had no cerebrovascular events, but one transient paraparesis case was observed. To avoid symptomatic spinal-cord ischaemia, some papers have indicated the importance of LSA reconstruction [19]. However, a recent study also reported that the LSA coverage during TEVAR does not mandate revascularization [20, 21]. We also think that the advantage of SG is that it is minimally invasive. Extra incisions are not needed except as the access route. However, if the LSA is reconstructed routinely, this advantage is reduced. Therefore, our original indications for LSA reconstruction comprised post-CABG patients with a patent left internal mammary artery (LIMA)–LAD and an inadequate right vertebral artery.

In left subclavian reconstruction cases, an extra-anatomical bypass of the right subclavian artery and LSA was performed routinely. That way, even if the left carotid artery is incidentally occluded by the FSG, the blood flow of the LSA is maintained and can keep at least the blood flow to the left vertebral artery. In contrast, if an extra-anatomical bypass of the left common carotid artery and LSA is performed, the left brain blood flow is completely compromised if the FSG accidently occludes the artery. However, using this strategy, we had a paraparesis case that developed due to simple left subclavian occlusion with a SG landing zone from Zone 0 to Th11. After having experienced this case, we performed a left subclavian reconstruction for patients at high risk of spinal-cord ischaemia, such as when the treatment of a long segment is necessary (the distal end of SG is beyond Th10). In our experience, there were clinical symptoms that accompanied the LSA occlusion in about half of the cases, but all symptoms improved within 6 months.

Another treatment option is the deployment of SGs with a side branch. However, few reports have described branched endografts for treating aortic arch disease. Inoue and colleagues described embolic cerebrovascular accidents as the major initial complication of branched SG implantation [22]. The risk of cerebral infarction also seems to be very high after deployment of a SG with a side branch, particularly when the brachiocephalic artery is involved. Side-branch devices can collapse and become occluded due to aortic arch remodelling, and an occluded aortic arch vessel might result in fatal cerebrovascular complications.

Our entirely endovascular procedure using a precurved FSG resulted in good periprocedural outcomes and mid-term durability. However, one group found that proximal graft deployment might increase mortality and morbidity [23]. The stroke rate was also notably higher given the more proximal extent of deployment. This might have been due to an increased incidence of atheroma and arch manipulation. Wires, catheters and devices can scatter embolic material at the orifices of the great vessels. Deploying an SG in the aortic arch is associated with anatomical problems. A sufficient landing zone cannot be secured in most of the patients, because the zone is short and is generally located too close to the great vessels and aneurysm. Seating the SG along the greater curve of a severely tortuous aortic arch is very challenging, and a thick vessel diameter adds further complexity. The SG might easily migrate due to high-pressure blood flow.

We therefore used original, J-shaped, long sheaths and customized the FSG based on the individual aortic arch configurations to overcome these problems. Endografts suitable for each patient were created from various stent frames and graft fenestrations based on preoperative 3D-CT imaging. Furthermore, these devices have an original tip-stabilizing system for exact endograft positioning in the aortic arch under normal blood pressure (Fig. 6).

In addition, the radial force of the stent frame is weaker than a conventional commercially available SG. For our device, the same diameter stent frames are used for any size of e-PTFE graft diameters. Therefore, as the graft diameter becomes larger, the radial force of the FSG becomes weaker. In addition, an e-PTFE graft is located outside of the custom-made stent frame. Therefore, when the e-PTFE graft receives blood flow, it expands enough using just the normal blood flow and pressure to snugly fit in the vascular intima without requiring a strong radial force of the stent frames. This concept resembles the sail of a yacht catching the wind. Therefore, during FSG deployment, blood-pressure control is not needed.

Our less-invasive, entirely endovascular procedure using a precurved fenestrated endograft with simplified manipulation of a long, J-shaped sheath decreased the incidence of neurological complications. Thus, high-risk patients will be able to tolerate this procedure. Nevertheless, the key to a successful outcome is a careful analysis of the preoperative 3D-CT findings to design the optimal fenestration of the SG and to evaluate the status of each patient.

The chief limitation of this study is the small number of patients and short follow-up time. However, we observed
acceptable outcomes for our procedure. Further long-term and prospective studies with a larger number of patients are required to validate our findings.

CONCLUSION

The short- and mid-term outcomes of endovascular repair of the aortic arch using an FSG seem to be acceptable based on this study. The technique is simple and less invasive than other procedures, and the device is potentially valuable for treating patients with aortic arch diseases who are at high risk for surgery. However, the outcomes were based on a small case series. Therefore, further studies in a larger cohort and a longer follow-up are required to confirm the outcomes.

We believe that this simpler therapeutic approach using a pre-curved fenestrated endograft will become a standard procedure for treating aortic arch diseases, which should maximize the benefit to patients.

ACKNOWLEDGEMENT

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Conflict of interest: none declared.

REFERENCES


APPENDIX. CONFERENCE DISCUSSION

Dr T. Schachner (Innsbruck, Austria): I think the evolution of endovascular therapy for arch aneurysms is important, especially to offer a treatment opportunity for high-risk patients in a complex disease. I have two questions for you. First, the consequence of migration of fenestrated stent grafts in the aortic arch is potentially disastrous. Would you be afraid of stent graft migration of these arch stent grafts, especially if you use it in younger patients, if you go down from high-risk to moderate-risk patients? In other words, what is your cut-off with regard to age for this treatment?

Dr Yuri: I think we can use it even in low-risk patients because there is rarely migration. In our experience, we have had no migrations of stent grafts.

Dr Bachet: But it is a two-year follow-up?

Dr Yuri: Yes. However, we have one case with six-year follow-up and there has been no migration.

Dr Schachner: Second, during the last years, the awareness and number of reports in the literature of retrograde aortic dissection have increased. There are even bigger series published which report a prevalence of maybe 1.5% to 2%. One of the risk factors for retrograde aortic dissection following TEVAR is a very proximal landing zone in the aortic arch or ascending aorta. What is your experience with this complication, even in the group of all aortic stent grafts, not only these 24 arch stent grafts?

Dr Yuri: Concerning this device, we had no dissection, although I have had one dissection with another device. This device we use has very low radial force, and the e-PTFE graft is outside of the stent frames, so I think it is safe from dissection.

Dr J. Bachet (Abu Dhabi, United Arab Emirates): This is an innovative and interesting topic. I have one question. As usual, in all the papers and presentations about arch debranching and stenting, the authors say that it is for high-risk patients, but as seen on your images, most of the aneurysms you have shown were very average aneurysms of low volume that could be operated on very easily through either a left thoracotomy or sternotomy. What was the risk in your patients? You did not tell us. Why did you use this technique instead of open surgery in those small aneurysms of the descending or distal arch?

Dr Yuri: Well, the high-risk patient is of older age and has pulmonary disease, cerebrovascular events, multiple surgeries. There are many problems.

Dr Bachet: But was this the case in those patients? You did not tell us.

Dr Yuri: Yes, they were just high-risk cases.

Dr Bachet: But do you have a score? Do you have a threshold? The problem is that we never know what the threshold of risk is. Do you decide, for instance, that a patient with an STS score more than 10 or a EuroSCORE more than 25 would be a high-risk patient and the rest would be normal patients, or is it just a gut feeling by the surgeons and the radiologists who say ‘Oh, I think this is a risky patient. Let’s do it?’

Dr Yuri: This study is ongoing, so I’m not sure.

Dr Bachet: I think it would be very important to indicate in all publications the threshold for high-risk patients and that the technique is used only above or beyond this threshold.

Dr Yuri: I know.

Dr Weigang: We have now heard three talks coming from Japan and we are all aware that you have very highly-skilled surgeons in Japan. However, I must admit to wondering why your results are so much better than in the rest of the world, even when you are treating patients with very new technologies. Do you have any idea why surgeons in the rest of the world have not been able to obtain similar results?

Dr Yuri: Sorry, I have no idea.

Dr Weigang: Perhaps this question is too difficult to answer.