

Factors predictive of distal stent graft-induced new entry after hybrid arch elephant trunk repair with stainless steel–based device in aortic dissection

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Objectives: Stent graft-induced new entry (SINE) has been increasingly observed after thoracic endovascular aortic repair of aortic dissection. We illustrate the possible mechanism by exploring predictive factors of late distal SINE after hybrid arch elephant trunk repair for aortic dissection.

Methods: From November 2006, to May 2011, 20 of 99 patients underwent hybrid arch repair using the elephant trunk graft as the proximal landing zone. After a mean follow-up period of 27.9 ± 12.0 months, 12 patients had late distal SINE events and the others were free of events. False lumen remodeling level was observed and maximal longitudinal diameter, average of longitudinal and transverse maximal diameter, circumference, and area of true lumen were analyzed for precise size selection of stent graft before and after the procedure. Taper ratio, true lumen:aorta ratio, prestent grafting oversizing ratio, poststent grafting oversizing ratio, and expansion mismatch ratio of distal true lumen were proposed and calculated for further evaluation of the mechanism of late distal SINE.

Results: Only the area oversizing ratio between true lumen and the distal selected stent graft at the presumed distal end of stent grafting was found as a significant predictive factor of SINE before procedure (4.00 ± 2.96 vs 1.98 ± 0.66 for SINE vs non-SINE, respectively; $P = .031$). The significant difference of the expansion mismatch ratio of true lumen between the 2 groups was found not only in the size measurement of mean diameter (1.48 ± 0.29 vs 1.22 ± 0.15 ; $P = .039$), but also in the area (2.39 ± 0.85 vs 1.58 ± 0.42 ; $P = .031$) and circumference (1.43 ± 0.27 vs 1.18 ± 0.14 ; $P = .016$) after stent grafting.

Conclusions: We found that taper ratio is not an optimal criteria for stent graft size selection and distal oversizing calculated by true-lumen area is a significant factor causing delayed distal SINE. Use of the prestenting area oversizing ratio should be limited. (J Thorac Cardiovasc Surg 2013;146:623-30)

Traditional surgical approaches for aortic arch repair, including hypothermic circulatory arrest, have been challenged by the hybrid elephant trunk procedure with the emergence of thoracic stent graft technology, which involves combining the advantages of open surgery with the less-invasive principles of endovascular implantation.¹ Because the elephant trunk technique allows repair of concomitant aortic arch and proximal descending aortic aneurysms in a single stage operation² and endografting for arch repair,³ the use of the elephant trunk as the proximal landing zone has not only changed the risk profile of the second stage operation but also provided the proper and secure proximal fixation zone for stent graft landing that avoids the diseased

and weakened dissected aorta. However, the distal landing zone of stent grafting is still located at the true lumen of the dissected descending aorta with a high incidence of late distal intimomedial injury induced by stent graft after implantation, as described in our previous work.^{3,4} Stent graft-induced new entry (SINE) has been increasingly observed after thoracic endovascular aortic repair (TEVAR) for Stanford type B dissection²⁻⁵ and distal SINE appears to be noticeably life threatening. Factors predictive of late distal SINE and preventions of SINE after hybrid arch repair using elephant trunk graft as proximal landing zone for aortic dissection were investigated.

MATERIALS AND METHODS

Patients

Between November 2006, and May 2011, 201 patients underwent TEVAR in our institute, the Taipei Veterans General Hospital. Ninety-nine patients had aortic dissection, including chronic type B and residual type A. Chronic aortic dissection type B is defined as event after 2 weeks. Residual type A is a condition in which dissection of the arch and descending aorta remains following aorta open repair of acute aortic dissection type A. The surgical indications are aneurysm rupture, intractable pain, refractory hypertension, ischemia of visceral or lower limb, and a maximal diameter of aneurysm >60 mm. Twenty patients (22%) who underwent hybrid arch repair using elephant trunk as proximal landing zone for stent

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Abbreviations and Acronyms

CT	= computed tomography
SINE	= stent graft-induced new entry
TEVAR	= thoracic endovascular aortic repair

graft enrolled in our study. This retrospective study was approved by the institutional review board at our institution.

Stent Graft System

Only the stainless steel-based stent graft (Zenith TX2, Cook Inc, Bloomington, Ind) was available before June 2010. That device is composed of stainless-steel Gianturco modified Z-stents covered with a polyester (Dacron) graft. The proximal element presents a proximal covered end with protruding barbs to secure it to the aortic wall and the distal end of the proximal component is fully covered. The distal component includes a covered proximal portion and a distal bare stent with barbs. Radial force over both ends of the covered segments facilitates landing zone seal and fixation.

Hybrid Arch Repair With the Elephant Trunk Technique

For patients with residual type A dissection or type B aortic dissection aneurysm, the hybrid arch elephant trunk procedure was performed through median sternotomy and under hypothermic cardiopulmonary extracorporeal support (23°C core temperature) as well as short temporary low circulatory arrest. Several types of adjunctive procedures were performed before thoracic stent graft implantation, according to different proximal landing zones. These procedures included carotid-to-left subclavian artery bypass, supra-aortic debranching, and arch and ascending aortic replacement.

The proximal stent graft size was selected according to the elephant trunk graft diameter with 20% to 30% oversizing. Taper devices were selected with a maximum 8 mm tapering, if 2 stent grafts were required.

A sheath of appropriate size was selected and inserted through femoral vascular access. The guide wire and pigtail catheter were advanced into the true lumen in a retrograde manner up to the ascending aorta under fluoroscopic guidance. One or 2 pieces of thoracic stent graft (mostly tapered, some nontapered) were then introduced along with the preset stiff guide wire and into the elephant trunk graft of the proximal landing zone. The proximal end of the stent graft was deployed across the elephant trunk anastomosis, which was securely fixed to minimize the possibility of distal migration in the future. During stent graft deployment, the patient's systolic blood pressure was lowered to <100 mm Hg to prevent both the windsock effect and distal migration. Further balloon molding was prohibited during the TEVAR procedure. Completion digital subtraction angiography aortography was finally performed to assess the correct position of the stent graft, the coverage of whole primary entry along the descending aorta, and the absence of endovascular leaks, as well as to assess the maintained patency of the supra-aortic trunks and the bypass grafts. Coil embolization for proximal left subclavian artery and/or ligation of the proximal left carotid artery were required to prevent type 2 endovascular leaks if the left subclavian artery and/or left carotid artery were covered by a stent graft. After the operation was complete, spinal cerebrospinal fluid drainage was established immediately if there were any symptoms of paraplegia.

Follow-up Imaging Protocols

Computed tomography (CT) was used to inspect the entire thoracic and abdominal aorta, including the bilateral carotid and iliac arteries. Helical 3-dimensional reconstructions were composed to assist graft length measurements and access conduit evaluation (iliofemoral arteries). Postoperative CT was performed 1 to 2 weeks after the procedure, then 3 months, 6 months, and annually after the primary TEVAR. Aortic size, diameter

of the true and false lumens, endoleaks, and characteristics of the stent grafts were evaluated in each patient. The occurrence and progression of new erosion or disruption of the intimomedial membrane of native aorta over the bilateral ends of the stent graft was documented.

The diameter, area, and circumference change of the true lumen of the proximal and distal segments of the descending aorta were measured both in the SINE and the non-SINE group by CT scan image.

The Extent Level of False Lumen Remodeling

The extent level of false lumen thrombosis was classified into no thrombosis (ie, within-stent level), partial thrombosis (ie, level between diaphragm and distal end of stent graft), and complete thrombosis (ie, diaphragm level). The extent of regression level (defined as false lumen obliteration) was also divided into 3 types, as described elsewhere.³

Data Collection and Analysis

CT imaging was performed using a Hi-Speed Advantage scanner (GE Healthcare, Waukesha, Wis) with settings at 5 mm collimation; 10 mm/sec-ond table speed; pitch = 2; and 120 kV, and 230- to 250-mA tube current. The Digital Imaging and Communications in Medicine data was transferred to OsiriX MD (version 1.1; <http://www.osirix-viewer.com>) for measurement and calculation of the true lumen orthogonal diameter, circumference, and area by multiple plane reconstruction technique.^{6,7} Three intervals of CT imaging were collected: CT imaging before and after primary TEVAR, CT imaging with first detection of distal SINE for the SINE group, and the last CT for the non-SINE group. Four proposed equations for precise size selection of stent graft before and after procedure were analyzed at the distal end level of the primary stent graft and at 2 cm away from the stent's distal end. These included measurements of longitudinal maximal diameter of true lumen (Figure 1, B), average of longitudinal and transverse maximal diameter of true lumen (Figure 1, C), circumference of true lumen (Figure 1, D), and area of true lumen (Figure 1, D). The diameter of elephant trunk graft (proximal landing zone) was also measured (Figure 1, A). Although the stent graft is presumably fully expanded, the proposed diameter, circumference, or area of distal end of stent graft was defined as the predicted distal stent size.

To evaluate the predictive factor of the late distal SINE event, 5 equations were proposed (Figures 1, 2, and 3).

$$TR = 1 - \left(\frac{X_A}{X_{Pro}} \right)$$

In this equation, taper ratio (TR)⁸ represents the ratio between the size of the elephant trunk graft (proximal landing zone) and the size of distal true lumen before procedure (Figure 1). X_{Pro} is the diameter of the proximal landing zone before the primary procedure (diameter of the elephant trunk graft, X_{ET} , in this study). X_A is the size of the true lumen at the distal end level of the primary stent graft before primary TEVAR.

$$PRGOR = \left(\frac{X_G}{X_A} \right) - 1$$

In this equation, pre-stent grafting oversizing ratio (PRGOR) represents the ratio between the distal size of the selected stent graft and the true lumen size at the presumed distal end of the stent graft before procedure (Figures 1 and 2). X_G is the distal size of the selected stent graft before the procedure.

$$POGROR = \left(\frac{X_G}{X_A} \right) - 1$$

In this equation, post-stent grafting oversizing ratio (POGROR) represents the oversizing ratio between the distal size of the limited-expanded stent graft after procedure and the true lumen size at the presumed distal end of the stent graft before procedure. These sizes are measured at the onset

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